EXHIBIT 2

UNITED STATES DISTRICT COURT.
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION — MDL NO. 2875
HON. ROBERT B. KUGLER

THIS DOCUMENT RELATES TO:
In Re: Valsartan, Losartan and Irbesartan Products Liability Litigation,
Case No. 1:19-md-2875-RBK

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HIGHLY CONFIDENTIAL REMOTE VIDEOTAPED DEPOSITION
OF LAURa PLUNKETT
THURSDAY, JANUARY 12, 2023
9:29 a.m.

Witness' Location:
Houston, Texas

TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter as taken by and before DAVID LEVY, a Certified Court Reporter and Notary Public of the State of New Jersey, held remotely over the Internet, on Thursday, January 12, 2023, commencing approximately 9:29 in the forenoon, pursuant to Notice.

A P P E A R A N C E S:
(All appearances are remote via Zoom conference.)

ON BEHALF OF THE PLAINTIFFS:
ADAM M. SLATER, ESQ.
MAZIE SLATER KATZ & FREEMAN, LLC
103 Eisenhower Parkway
Roseland, New Jersey 07068
973-228-9898
aslater@mazieslater.com

ON BEHALF OF THE PLAINTIFFS
BRETT VAUGHN, ESQ.
MELISHA VELEZ, ESQ.
THE HOLLIS LAW FIRM
8101 College Boulevard, Suite 250
Overland Park, Kansas 66210
913-385-9400

ON BEHALF OF THE PLAINTIFFS:
STEVE LEVIN, ESQ.
DANIEL NIGH, ESQ.
LEVIN PAPANTONIO RAFFERTY PROCTOR BUCHANAN O'BRIEN BARR MONGEY P.A.
316 South Baylen Street
Pensacola, Florida 32502
850-435-7003
slevin@levinlaw.com
dnigh@levinlaw.com

ON BEHALF OF DEFENDANT SCIEGEN PHARMACEUTICALS, INC.
KATHLEEN E. KELLY, ESQ.
HINSHAW & CULBERTSON LLP
53 State Street, 27th Floor
Boston, Massachusetts 02109
617-213-7047
kekelly@hinshawlaw.com

A P P E A R A N C E S (Cont'd):
ON BEHALF OF THE DEFENDANTS HETERO LABS AND HETERO DRUGS:
ERIC ABRAHAM, ESQ.
JOHN C. BOBBER, JR.
HILL WALLACK, LLP
21 Roszel Road
Princeton, New Jersey 08540
609-924-0808
eabraham@hillwallack.com
jbobber@hillwallack.com

ON BEHALF OF THE DEFENDANT TEVA PHARMACEUTICALS USA, INC.
STEVEN M. HARKINS, ESQ.
VICTORIA DAVIS LOCKARD, ESQ.
GREENBERG TRAURIG, LLP
3333 Piedmont Road NE, Suite 2500
Atlanta, Georgia 30305
678-553-7392
harkinss@gtlaw.com
lockardv@gtlaw.com
-and-
CHRISTINE I. GANNON, ESQ.
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
One Mulberry Street, 15th Floor
Newark, New Jersey 07102

ON BEHALF OF DEFENDANT ZHP
JESSICA D. MILLER, ESQ.
ANNA BRIER, ESQ.
TARA KOHLI, ESQ.
SKADDEN ARPS SLATE MEAGHER & FLOM LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
212-371-7134
anna.brier@skadden.com
tara.kohli@skadden.com
jessica.miller@skadden.com
-and-
BRIAN BAGGETTA, ESQ.
SKADDEN ARPS SLATE MEAGHER & FLOM LLP
One Manhattan West
New York, New York 10001
202-371-7209
brian.baggetta@skadden.com

A P P E A R A N C E S (Cont.d):
ON BEHALF OF THE DEFENDANT MYLAN N.V.
FRANK H. STOY, ESQ.
PIETRAGALLO, GORDON, ALFANO, BOSICK & RASPANTI, LLP
301 Grant Street, 38th Floor
Pittsburgh, Pennsylvania 15219
412-263-4397
fhs@pietragallo.com
mbcatello@pietragallo.com

FOR THE DEFENDANT TORRENT PHARMACEUTICALS
BRITTNEY NAGLE, ESQ.
KIRKLAND & ELLIS, LLP
601 Lexington Avenue
New York, New York 10022
212-909-3344
brittney.nagle@kirkland.com

FOR THE DEFENDANT HUMANA
MEGAN A. ZMICK, ESQ.
FALKENBERG IVES, LLP
230 West Monroe, Suite 2220
Chicago, Illinois 60606
312-566-4801
maz@falkenbergives.com

FOR THE DEFENDANT ALBERTSON'S LLC
CHRISTOPHER B. HENRY, ESQ.
BUCHANAN INGERSOLL & ROONEY, P.C.
Carillon Tower
227 West Trade Street, Suite 600
Charlotte, North Carolina 28202-2601
704-444-3300

ALSO PRESENT:
LEE BOWRY, Videographer
GREGG HOLDERMAN, Concierge

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VIDEOGRAPHER: Stand by, everyone. We'll be underway in about ten seconds.

Good morning. We are going on the record at 9:29 a.m. on January 12, 2023. Please note that this deposition is being conducted virtually. Quality of recording depends on the quality of camera and about the connection of participants. What is spoken from the witness and heard on screen is what will be recorded. Audio and video recording will continue to take place unless all parties agree to go off the record.

This is media unit 1 of the video recorded deposition of Dr. Laura M. Plunkett in the matter of in re, Valsartan, Losartan and Irbesartan products liability litigation filed in the United States District Court for the District of New Jersey, Camden vicinage, MDL number 2875.

My name is Lee Bowery, representing Veritext New Jersey. I am the videographer. The court reporter is David Levy, and the concierge is Gregg Holderman, both also with Veritext.

I am not related to any party in this action, nor am I financially interested in the outcome. If there are any objections to proceeding, please state them at this time.

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Having heard none, counsel attending remotely will be noted on the stenographic record. Will the court reporter please swear in the witness and then counsel may proceed.

L A U R A M. P L U N K E T T , having been duly sworn by the Notary Public, was examined and testified as follows:

MS. MILLER: May I proceed?

EXAMINATION BY

MS. MILLER:

Q. Good morning, Dr. Plunkett. Thank you for your patience this morning. Can you just please state your full name for the record.

A. Laura Massey Plunkett.

Q. Great. I know you've been deposed many teams, and so given especially that we have lost a little time this morning, I am going to forego providing you with the rules of depositions. I think we all know them, and I'm just going to get straight into the matters we're here to discuss today. Does that sound good?

A. That's fine.

Q. Great. You understand that I'm here to discuss opinions you're rendering as an expert for Plaintiffs in the MSP Valsartan case, correct?

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A. Yes.
Q. And do you know who MSP is?
A. No.
Q. Do you know who the Plaintiff is in this matter?
A. The names of the Plaintiffs, no.
Q. What's your understanding of your role in this litigation?
A. I was engaged to provide opinions related to -- it's in my report, related to the toxicology or genotoxicology of the impurities found in Valsartan that are known generally as nitrosamines. And in this particular deposition, two specific ones. MDMA and NDEA. I'm just going to abbreviate them.
I was also asked to provide general regulatory opinions related to the way that these are generic drug products, the way the generic products are regulated generally by the FDA, the role and responsibilities of manufacturers of both active pharmaceutical ingredients, and if we can agree, I'll call them APIs, and then what I call finished dose products, so that would be the products that are actually the subject of the, what I call Abbreviated New Drug Applications, or ANDAs, in this case.

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Q. Are you offering a causation opinion?
A. No, I'm not. I'm not a causation expert as it relates to injuries, if that's what you mean by causation.
Q. Are you offering an opinion that the use of Valsartan contaminated with NDMA can cause cancer?
A. I believe I did have that on my report as it relates to what was known or is known and has been known over the decades about the risks posed by Valsartan. I have a couple of paragraphs where I talk about sort of the -- both the general toxicologic community believes is true or knows is true about the risks, the cancer risks posed by exposure to the impurities of Valsartan.
Q. Are you offering an opinion that the levels of NDMA contained in Valsartan can cause cancer?
MR. VAUGHN: Object to form.
A. I don't believe I have that specific opinion, no. But I certainly do have opinions in the report, if you've read it, that I talk about the fact that is presence of the impurities increases the risk for cancer generally, and that the poses a hazard and puts patient safety at risk.
Q. Have you quantified how much you believe

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the presence of impurities increases the risk of cancer for Valsartan users?
MR. VAUGHN: Object to form.
A. Are you asking me have I done an independent risk calculation or done a risk assessment to come up with a level of cancer risk, is that what you're asking?
Q. Let me put it more simply. I believe you testified that the presence of impurities in Valsartan increases the risk of cancer, right?
A. Yes.
Q. Do you have an opinion on how much it increases the risk of cancer?
MR. VAUGHN: Object to form.
A. I don't have a -- I haven't done -- that's why I asked the question that I did. I mean, too answer that question, I would typically say, have I calculated a -- a risk value independently, and I have not done that. I think that's what you're asking me. That's how I would describe what you're asking for. And so I have not done that. I'm aware that there have been others. If you go to the toxicology literature and even to different documents off the -- produced by different regulatory authorities, the issue of increased risk can be a

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specific issue for a specific exposure pattern. And I'm not specific causation, so I haven't done those kinds of calculations.
Q. So if you haven't calculated the risk and value, how do you know there is actually an increase in risk?
MR. VAUGHN: Object to form.
A. Because of the -- what is understood about cancer and these particular compounds. Do you want me to explain?
Q. Have you determined whether the dose of NDMA and NDEA in Valsartan was sufficient to increase the risk of cancer?
MR. VAUGHN: Object to form.
A. The answer -- a you're asking a question that has to do with specific -- a specific situation for specific person maybe taking Valsartan at a specific dose over a period of time. That's the best way to answer that question. Or that's actually the scientifically defensible way to answer the question. Do you want me to explain a little bit why I am answering that way? I'm happy to give you a little background on risk assessment and how it applies.
Q. No, because my question really is, how much Valsartan would a person have to take to

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increase their risk of cancer?
MR. VAUGHN: Object to form.
A. Well, it's not the Valsartan. It's taking in the impurities of the Valsartan. So the Valsartan itself, by itself, if you were to have a hundred percent pure Valsartan, that's not the compound that I'm referring to that will increase risk of cancer; however, it's the impurities in the Valsartan, and nitrosamines, specifically NDMA and NDEA, that are in the compound; and we assume when you take Valsartan in this case, the evidence in the date that has shown you're taking in those impurities. It's the presence of those impurities that are increasing the risk of cancer. If they made Valsartan without those impurities, the cancer risk is not there.
Q. Understood. But my question is, if somebody took one Valsartan pill during the class period that had these impurities, did that person have any increased risk of cancer?
MR. VAUGHN: Object to form.
A. That's beyond the scope of what I did, thank you. I did not do calculations based on exposure assessments. It's my understanding that there are other experts in this litigation that are

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either what I call risk assessors or specific causation experts that are doing those types of assessments. And that was beyond the scope of what I did. I think if you read my report, I hope you understand what it is that I've done, based upon my description of the facts and the other information.
Q. You did say you're testifying that the presence of impurities in Valsartan increases the risk of cancer. And I'm asking what is the minimal doses at which that happens?
A. And again, I'm answering it to you, I already have, in the literature -- this is where I need to explain. I'm not trying to be nonresponsive, but let me just step back a second and state that if you remember, you understand as I said that I believe that NDMA and NDEA have been identified by authoritative bodies as carcinogens, probable human carcinogens, based on the data that's there. If you -- with that in mind, and looking at what this drug, what the FDA has said and what other, how you would approach risk assessment for these kinds of products in the context of pharmaceutical risk assessment or risks are looked at in the context of benefits, in this case, you're talking about how does the risk of cancer balance against what is going on

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with the drug. And as a result of that work, I'm saying to you that it's very clear as a toxicologist, pharmacologist, risk assessor, someone who works in regulatory affairs, that the presence of this ingredient in Valsartan, where there is no known safe dose generally of these impurities, that it applies to any particular individual, because you have to do this on an individual basis based upon their exposure assessment; but generally the statement is that it increases the risk of cancer. It increases the risk in that particular person that you may want to consider that they would have an outcome of cancer.
And then from that, the role of the specific causation expert or the risk assessors in the litigation would be to talk about the specific level of exposure. So that's why I'm saying that's beyond what I did. I looked at this from the aspect of the regulatory expert, as a toxicologist, what do I know, and I know that these were probable human carcinogens. They are not supposed to be in the Valsartan, or the presence of them as very potent genotoxins increases the risk of cancer.
Q. Your risk opinion is completely untethered to any dose?
MR. VAUGHN: Object to form.

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A. What do you mean by "untethered to dose"? Are you asking --
Q. Are you saying --
A. -- whether it would change depending upon whether it was detectable or not detectable?
Q. No. I'm asking, are you testifying that that the impurities increase the risk of cancer regardless of the dose of Valsartan with the impurities that a person took?
MR. VAUGHN: Object to form.
A. The way you're asking the question is what I'm having trouble with. So there's -- my opinions relate to whether or not, in the population of people that could be -- that were exposed to Valsartan, there an increased risk of cancer. It's a population-dependent -- just like FDA does, when they do assessments for drugs and look at risks, they look at it across generally the population of people taking the drug. So that's what I'm stating to you about risk, increased risk.
Then, where you're going, when you're talking about the dose, then you have to look at what different exposure patterns were for individuals. FDA has said, if you read their different statements about the presence of these impurities in Valsartan,

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that these particular impurities are ones that are known to be associated with the risk of cancer, and that's what I'm saying. These increase the risk of cancer if you take them. They are associated with that risk. And then from there, for any one individual person, which is beyond the scope of what I did, others are doing that, they can tell you for that individual at what that risk might be in terms of quantifying. Because I think that's what you're asking. I think you're asking to quantify.

Q. Do you have an opinion as to whether someone who took one Valsartan pill during the period when it contained an impurity, whether that person is at an increased risk of cancer?

MR. VAUGHN: Object to form.

A. That is not the opinion I've stated in my report, or addressed, because that was beyond the scope of what I was asked to do. Again, it's my understanding that others in the litigation are handling the issues related to daily doses of Valsartan and the doses of the impurities and how those relate to individual injuries.

Q. Do you consider yourself to be an FDA expert?

A. I consider myself to be an expert in the

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FDA regulations as they apply to products that are currently regulated by the U.S. FDA, yes.

Q. Have you ever described yourself as an FDA expert?

A. It's possible. I don't know if I've used those exact words, if that's what you're asking me. I think in my report, I talk about being an expert at FDA regulated products or the regulation of products.

Q. Do you recall sitting here whether you've ever described yourself as an FDA expert?

A. Are you asking me if I ever used just those words? I don't know, it's possible I did.

Q. Have you ever worked at FDA?

A. I've never been an employee of the FDA, no.

Q. Have you ever been a consultant for the FDA?

A. A hired consultant, no. I've represented clients before FDA before. And I interface with them. But I am not an employee, I've never been an employee, and I've never been hired as a consultant, no.

Q. When were you first contacted about potentially serving as an expert in this litigation?

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A. I don't have an exact date. If you look at my billing, that -- I don't have bills in front of me but I know you've been provided those. Those give you an idea of the dates that are involved with my work on the case and I would have been contacted or hired sometime before that, sometime probably a year before the first work was done.

Q. A year before?

A. Sometime during the year before the first work was done. I can't give you an exact date.

Q. So you don't recall when you -- whether it was 2022, when you were first contacted?

A. Oh, it was not 2022, no. It would have been before that, during COVID, so in fact, again, I don't have an exact recollection but my -- I have a lot of cases like this one, that have been long delayed from the typical time period because of the issues related to the pandemic and the way courts have moved much more slowly during that time.

Q. Do you recall when you agreed to serve as an expert?

A. If you have the -- I believe I signed a confidentiality for documents, so that would be right around the time or right before the time -- right after the time that I agreed to serve, yes.

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Q. And --

A. And I don't have that in front of me this morning. You should have that in your files, I would think.

Q. Between being asked to serve as an expert and agreeing to serve as an expert, did you do research on Valsartan?

A. No, because I had already done it years before that. I was -- to explain that, I was well aware of what was going on with Valsartan from the time that it first appeared in what I called the trade press back in 2018, and there was first knowledge -- I was aware of the fact that there had been recalls, that the FDA was addressing the issue and it's -- the reason I was aware of it is because I'm a cardiovascular pharmacologist as part of my expertise, and I have an interest in following drugs in the classes that are part of my very specific training and experience.

Q. Have you ever published any articles about Valsartan?

A. No, I have not. Although I have published articles related to the role of the angiotensin system in control of the autonomic nervous system included blood pressure.

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Q. Have you ever published any articles about nitrosamines?
A. No, I have not.
Q. Have you ever given any speeches about Valsartan?
A. No, I have not.
Q. Have you ever give any speeches about nitrosamines?
A. I've never given a speech that was only on nitrosamines, but certainly nitrosamines are compounds that I may have had mentioned in speeches where I talk about cancer, cancer risk assessment.
Q. Have you ever consulted in connection with a product that contained NDMA or NDEA prior to this litigation?
A. I don't believe it was related to product, no.
Q. What do you mean by that?
A. So NDMA and NDEA, I've looked at the issues that cancer was developed from nitrosamines in the past, and I've looked at the animal data in the past, back when some of those studies first appeared I think in the '90s, to early 2000s. So I have looked at the data related to these compounds before, it's my understanding that, you know, I mean, my

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knowledge that these are kind of prototypical carcinogens. If you want a positive control animal study, NDMA for example would be a good positive control to use when you're testing for cancer.
Q. Have you ever advised a company on the risks associated with NDMA and NDEA?
A. No, I don't -- I've never had a client who had those detected in their products.
Q. Have you ever worked with a solvent, DMF, dimethylformamide?
A. Formamide. Can you please be more specific? I think you said work. Did you say "work"? What do you mean by "work," have I ever come across it, have I ever given it to an animal, what are you asking?
Q. Have you ever done any professional work involving that solvent?
A. Well, it's still a really broad question, I would argue, but certainly it is a compound I've heard of before in my work but it isn't that I've ever, like, drafted a toxicology profile or done any specific testing where I've -- that's been involved with that particular compound, no.
Q. Have you ever done any lobbying involving a product that contains DMF?

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A. I don't -- I'm not a lobbyist. What do you mean by lobbying?
Q. Have you ever done any lobbying?
A. I'm not a lobbyist. So are you asking me have I ever -- ever argued or had a meeting where I've taken a position one way or the other, is that what you mean, as a scientist? Because I have not, no.
Q. Have you ever worked with a company that manufactured a product using DMF?
A. I have no idea.
Q. Have you ever advised any companies about the risks of degradation of DMF?
A. Not that I can recall, no.
Q. When did you first have knowledge that DMF can degrade into diethylamine?
MR. VAUGHN: Objection, foundation.
A. So, I don't know that I can answer that with any clarity, not knowing, not being able to say whether or not in the past I've ever reviewed information on that. It's very possible I have in the past, but it's never been something that's been top of my head. Certainly I'm aware of it based upon the reports I've read on -- from Dr. Hecht in this case, and also from the top deposition testimony of

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some of the people, the witnesses for ZHP in the case.
Q. Prior to being contacted about serving as an expert in this litigation, did you personally have knowledge that DMF could degrade into diethylamine?
MR. VAUGHN: Object to form.
A. I don't recall ever having that as something that I could say that I was asked about. So, I mean, I -- that's the best I can answer it for you. It's not been a focus of any work that I can recall in the past.
Q. Have you ever been, prior to being contacted about serving as an expert in this litigation, did you ever have knowledge that the TEA process used by ZHP could lead to the formation of NDEA?
MR. VAUGHN: Object to form.
A. No, because I wasn't aware of ZHP's TEA process until discovery documents in this case became available. That's when I became aware of what it was that they had been done in terms of understanding how they produced thee product.
Q. Prior to being contacted about serving as an expert in this case, did you personally have

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knowledge about how any chemical process could lead to the formation of NDEA?
MR. VAUGHN: Object to form.
A. NDEA? Um -- yes. I mean, I have reviewed the toxicology literature over the years related to these types of impurities and actually, in the EPA projects I've worked on, on the carbon contaminants in that particular case, which is a little different than the FDA world. But yes, I have reviewed the formation.
I have some -- in fact, the structures that I put into my report come from one of my textbooks, and I've reviewed that section and that chapter of the textbooks several times in the past, so I have that awareness. But I've never worked -- I had not, you know, I have not developed a report before for anyone, none of my clients ever approached me to put together a tox profile on NDEA specifically. So it's more general of understanding and training based upon the toxicology training I've had.
Q. Can NDEA be formed with tertiary amines, or amines?
MR. VAUGHN: Objection, form, foundation.

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A. So that's beyond the scope of what I -- what I have done in terms of coming and being able to understand or describe all of the ways it can be formed. Certainly, I'll refer you to Dr. Hecht or all the other experts, chemists in the litigation to describe those kinds of details. There was an understanding in this case based upon what processes are described; and so if you want me to pull all those documents, we can go back and look at what was described in the particular documents related to this case.
Q. Prior to reviewing the documents in this case, did you have an understanding as to what sort of amines were necessary and what alkyl groups were necessary to form NDMA and NDEA?
MR. VAUGHN: Object to form and foundation.
A. I can't say that I would have been able to describe those for you in any detail before looking at these documents, no. But I can tell you that certainly, it is -- it was something that was known in this literature, and I agree with that because I went back and I looked at some of the exhibits that were used in the depositions that talk about the foreseeability, I've read Dr. Hecht's

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report and his description of some of these reports.
Q. When you talk about the exhibits used in depositions, you're talking about the textbook that you cite and the Tetrahedron article you cite?
MR. VAUGHN: Object to form.
A. That I mention in my report, yes. Those are the two that I saw, they were described in the -- by Dr. Hecht. But they have also described, they are asked about within the deposition of one of the witnesses or several of the witnesses for ZHP, the depositions I read.
Q. Have you seen the Australian textbook before serving as a expert in this litigation?
A. That was not one I had in my files, no.
Q. And had you seen the Tetrahedron article before serving as an expert in this litigation?
A. I don't recall, but I don't know, based on the number of years it's been since I've been asked specifically these kinds of questions before by any client.
Q. Are you a regular reader of the Tetrahedron Journal?
MR. VAUGHN: Object to form.
A. What do you mean by "regular reader," do you mean do I subscribe? Is that what you're asking?

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Q. Sure.
A. It's not one I subscribe to, no. But it certainly is a journal that comes up routinely when I do searches for projects I've worked on. Tetrahedron is one that publishes chemistry articles, specifically those that deal with any toxic compounds.
Q. Sitting here today, can you identify any literature besides the Australian textbook and the Tetrahedron article that addresses whether and when DMF can degrade into diethylamine?
MR. VAUGHN: Object to form.
A. That was beyond the scope of what I did. I didn't do that search. I could but I haven't done that. I didn't feel I needed to do that in order to provide the opinions I did in this case, because there is a chemist that's doing that kind of work.
Q. You do provide an opinion that it was known in 2012 that DMF could degrade into diethylamine, right?
A. Yes, based on that -- I think if you read my report I talked about the fact that when a company is doing a risk assessment, part of that would be search of the published literature to make sure there is something that is out there that they

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may not be aware of. So certainly, that's why I have formed those opinions. If I was to do a risk assessment for looking at something about the process that's being used, I could look at what the potential byproducts or degradation products or pathways that could be affected by using this particular chemical process. And so that's why those articles are important, because it shows what was known at different points of time and, most importantly, what was known before the issues arose in this case about the breakdown of -- or the use of the chemical process that led to the presence of the NDMA and NDEA in the Valsartan API.

Q. The only published literature you cite on those topics is published literature that was used by Plaintiff counsel in depositions, correct?

A. Yes. And again, that's because that was beyond the scope of what I was asked to do. I was not asked to be the chemist to address that specific question in a complete and expansive manner.

Q. So your opinion of this was widely known, is based on documents that you obtained through this litigation, correct?

MR. VAUGHN: Object to norm.

A. Well, depends. I also have -- I also --

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well, not entirely -- are you asking me specifically just about the issue of breakdown or the formation of DMF for example, that's what you're asking me?

Q. Correct.

A. That would be true that -- because again, that was beyond the scope of what I did independently, but it's evidence that's important to me in my opinions because one of the issues that you have as a regulatory expert is understanding what a company could or should have done if they had been following all the regulations and been complying fully with what they are required to do in the literature to produce a human prescription drug product.

Q. I understand, but my question is really simple. Your opinions of what the company could and should have known are based on documents you obtained in this litigation, correct?

MR. VAUGHN: Objection.

A. That and their own deposition testimony. So the company -- ZHP company witnesses also agreed to that issue, that these are things that could have been known. They had not done a rigorous assessment.

Q. What ZHP witness said that they did not do a complete risk assessment?

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A. So there's a stipulation document that's in the paragraph, paragraph 45 in my report, where I say that the lack of full evaluation of chemical processes have been stipulated to by Defendants. So evaluation -- full evaluation is what I'm talking about in terms of the risk assessment.

Q. Before you were contacted by Plaintiffs in this litigation to serve as a paid expert, did you do anything to warn the public about the use of Valsartan that contained nitrosamine impurities?

MR. VAUGHN: Object to form.

A. So that's a really broad question. Are you asking me a specific action that I took to maybe write an article or are you asking me about conversations? What are you asking me about?

Q. I'm asking about it all.

A. Well, I did have conversations with some of my acquaintances, my colleagues, my family members who were taking these drugs, who asked me questions about it, when they saw the information in the popular press.

But I did not reach out to FDA, for example. FDA was already aware, and I know this because they were taking actions. I did not reach out in any manner to any other type of -- other

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company or -- but I certainly did have conversations with individuals that reached out to me.

Q. Did any family or friends ask you whether they should continue taking their Valsartan until there was -- until, you know, the market has sufficient availability of alternatives?

MR. VAUGHN: Object to form.

A. That's not the question they asked, because I'm not a physician. They asked me what did I think about the issues and whether or not there was a risk.

Q. And what did you tell them?

A. I told them I did believe there was a risk based upon the fact that it is something that wasn't meant to be in the products, and most importantly, it increases the risk -- it's a potent genotoxin and is known to increase the risk of cancer; so in my opinion as a toxicologist, I would not want to be taking a product that had these impurities in it.

Q. I've always heard the expression that when it comes to toxicology, one of the major tenets is that the dose is in the poison, or the poison is in the dose. Is that a true -- an expression that's used in toxicology?

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MR. VAUGHN: Object to form.
A. It is a term that's used. But there's a different -- there's a different sort of methodology or way for assessing risk and dose issues with cancer versus non-cancer. So that's absolutely the issue of threshold mechanism or a threshold existing for things that are doing, actively to produce effects that are not cancer.
You can typically find a threshold if you do enough studies or do enough looking. However, for cancer risk assessment, if the assumption is that there is no threshold, so as a result, the dose makes the poison can apply, but it's not to the same extent or level as it does when you're talking non-cancer endpoints.
Q. When you describe something as a potent genotoxin, in order to determine when it's a potent genotoxin, do you need to know what dose the person is exposed to?
A. I'm not talking about as a person, I'm talking about based upon scientific evidence. And by "potent genotoxin," I'm describing the fact that the studies that have been done, genotoxicity studies are typically done in vitro. There are some in vivo studies but most of it's done in vitro. And in those

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studies, when you compare, again when you look at cross-compounds, NDMA is often a positive control compound. It's used to make sure your assay is working properly.
So in other words, it is reliably going to produce a genotoxic insult when you expose cells to it, and the potency has to do with the fact that you can get those kinds of DNA changes or changing mutations at very low exposure levels.
Q. When your family members or friends came to you and asked if they were at an increased risk of cancer, did you tell them it depended on how much Valsartan, how much DMA they had consumed?
MR. VAUGHN: Object to form, foundation.
A. No one asked me to do that for them. They were more interested generally with the issue should they have a conversation with their doctor and consider whether or not they should be changing to a different drug. They didn't ask me, should they change; but my advice was, I mean, "Talk to your doctor, but if it was me, I would be talking to my doctor about switching to a drug that did not have that impurity, those impurities in them."
Again, the FDA in themselves state that the NDMA and the NDEA in these nitrosamine impurities

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are unacceptable and are not supposed to be in the product.
Q. Okay. When you said you advise them to switch to a drug that doesn't have those impurities, at that point, Valsartan had already been recalled and off the market, correct?
MR. VAUGHN: Objection, form, foundation.
A. So when the individuals, or an individual approaches me about asking these questions, this is something that has gone on for a while, that is true. But it's also my understanding that even though there had been recalls, there was a continually finding an issue with the presence of these impurities in the drug.
And also, the other thing that I talked to individuals about is the fact that the presence of these impurities from my understanding and reading what FDA's investigations showed had to do with problems at the companies related to their manufacturing policy. So those kinds of conversations were had.
It's more than just -- the questions I was asked was more as friends and people that I know coming to me and saying, "As a toxicologist, would

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this be something that you would want to be exposed to, should I worry about this?" And I said, "I would worry about it. It's something that you don't want to take, it's not supposed to be there, there are potentially alternatives, but you have to talk to your doctor because I'm not a physician."
So I didn't say, "Please change to this, or please change to that."
Q. Right. But by the time they came to you, they could no longer purchase Valsartan because it had been recalled, correct?
MR. VAUGHN: Object to form, foundation.
A. Well, I can't tell you whether or not anybody still had it in their possession. If somebody had been on Valsartan for a while they may have still had the drug in their -- that's beyond the scope of conversations that I've had --
Q. How many of these individuals were there who came to you with these questions?
A. At least three or four people that I know.
Q. And some were family and some were friends?
A. Yes.
Q. And when they asked you, "Am I at risk,"

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you did not ask them, "What is your dose of medication," correct?
MR. VAUGHN: Objection, misstates prior testimony.
A. That -- I did not do a risk assessment for any individual. What I did was, people came and asked me whether this is something they should worry about, what did I think about the -- about these particular impurities in the product. And my answer is, they can increase their risk of cancer, they are known genotoxins. I wouldn't be taking a drug with those, if I -- if it was me, I would talk to your doctor.
Q. Have you ever done a study that was funded by Plaintiffs' lawyers?
A. I don't believe so. Other than the -- by "study," you mean a test or a clinical study or an animal study, I have not. No.
Q. Do you intend to publish any of your theories related to this litigation in the peer-reviewed literature?
A. I have not done so, and I don't right now have a plan to do so. Typically I wouldn't do so without understanding what limits or constraints there may be in terms of confidentiality agreements

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that I've signed in terms of the documents I've reviewed.
Q. Have you ever advised any pharmaceutical companies on medications?
MR. VAUGHN: Object to form.
A. You need to be more specific by -- what do you mean, "Advise pharmaceutical companies on medications"? That's a really broad question.
Q. I'd like to know the names of all medications for which you have provided consulting services to pharmaceutical companies.
MR. VAUGHN: Doctor, to the extent that you are not under a confidentiality agreement, you may answer the question.
A. So most of the work that I do, have done over the years with companies is considered confidential. I don't even share names. Companies typically that I'm currently working for, because that's part of my business terms and part of the agreements that I'm asked to enter into by companies.
I have testified before that in my, over my 30-plus years experience, I have worked on projects related to many of the largest drug companies around, and many small companies as well. But I don't feel that it's something that I could do

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to divulge the specifics of a project without asking a company to do that, if I could do that or not.
I assume you're limiting that to regulatory consulting. You're not asking about the litigation work, because that you could find, when you -- if you look at my trial work.
Q. Have you over done any litigation work on behalf of a pharmaceutical manufacturer?
A. Yes. I did litigation work on behalf of pharmaceutical manufacturers when I was working with Environ between 1989 and 1997. They only worked for industry in litigation. And there is a most recent time would have been, probably about ten years ago, I worked for a company, a Japanese company on an issue that was being litigated. A Japanese drug company.
Q. What was the drug?
A. Oh, gosh, I don't remember the name off the top of my head. A blood pressure medicine, but I don't remember the name off the top of my head.
Q. Do you know if that blood pressure medicine was ever found to have NDMA or NDEA?
A. Those were not the issues that I am remembering from my work on the case, so I can't tell you if it did. I just, that was not what we were addressing or I was addressing.

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Q. Did you advise that company about the potential risk in development of NDMA or NDEA in blood pressure medication?
A. Already said it was not the issue of the case. There were no issues about nitrosamines or NDMA or NDEA in that particular case.
Q. I understand that. I'm just asking if you happened to mention that issue to the company.
MR. VAUGHN: Objection, asked and answered.
A. No, it was ten years ago. I don't think I would have, no.
Q. And in the last ten years, have you done any litigation work on behalf of a Defendant pharmaceutical company?
A. Defendants, yeah. For pharmaceutical companies, no. Not in litigation. I have consulted with companies, but not litigation.
Q. Do you know of any medications besides Valsartan that have had issues with NDMA or NDEA?
MR. VAUGHN: Object to form.
A. There certainly is -- have been -- have been drugs mentioned on the FDA website and the trade press, yes.
Q. Which other --

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A. Other sartans. Losartan I think is one, Metformin is one I've seen, I don't know. To get the complete risk, I'd refer you to the FDA site.
Q. Understood. I'm just asking which ones you know about.
A. Off the top of my head, those are ones that I can recall.
Q. Just the sartans and Metformin?
A. Yes. There's others. I just don't remember the names off the top of my head.
Q. Are you serving as an expert in any other nitrosamine litigation right now?
A. No.
Q. Have you ever served as an expert in any other nitrosamine litigation?
A. No, I have not.
Q. When did you first form the opinion that Valsartan that contained NDMA and/or NDEA impurities was adulterated?
MR. VAUGHN: Object to foundation.
A. The opinions that I've expressed in my report, where I talk about the products that would be deemed adulterated, would have been developed at the time I wrote the report so then before the date of the report, October 31st, would have been sometime

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earlier in 2022. I can't give you an exact date. And I would state that the -- and those opinions were developed based on a review of findings of FDA along those lines, where they actually sent a warning letter related to that.
Q. When did the FDA send a warning letter -- when did the FDA first send a warning letter with the word "adulterated" in it?
MR. VAUGHN: Object to form.
A. I want to say that there's a warning letter that I'm aware of in 2019. I don't know if there were other warning letters that existed. I don't know and the one I'm thinking about is one that went to ZHP.
Q. Do you hold the opinion that Valsartan was adulterated before that -- before 2019?
A. It's my opinion that it would have been deemed adulterated based on what was -- what the evidence in the case appears to show, yes.
Q. What --
A. Based on --
Q. -- I didn't mean to interrupt you. So sorry.
A. No, go ahead and follow up, because I think you were going to ask it of me, right? If

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that's what I mean by that. I mean that -- if the facts and evidence in this case show that at least at the time that Novartis identified -- I described this in my report in 2018 to ZHP -- the presence where they had found it, the presence when it's found indicates that it's adulterated because it is not something that was meant to be there, and it is a potent genotoxin, and that's been known from well before that time period.
In this particular case, there's also facts and evidence to indicate that as early as the 2014 time frame, the company, being ZHP, was making product where there were unidentified peaks that they were not pursuing. So the presence of those impurities, the fact that for a time raises questions about the quality of the product, even though they had not identified those particular ones at that particular time as being, for example, NDMA.
However, if they had done, if the company had done the proper risk assessment, chemical process assessment at the time that they changed from the TIN process to the other process they were using, I believe, it's my opinion that the risk assessment would have gone led to, potentially, some knowledge about this issue and that I think is also the opinion

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of Dr. Hecht and others in this case. He addresses that more directly than I do.
I happen to rely on what I see described in the documents and facts as they present it, and I describe in my report.
Q. What specific things should ZHP have done in its risk assessment that it didn't do, like what specific tasks?
MR. VAUGHN: Object to form.
A. I don't think I could -- I don't think I have laid out a set of specific tasks in my report, but I would tell you that in my report, as I describe, the risk assessment process is understanding breakdown byproducts, degradation products that could occur and with -- as Dr. Hecht has explained, I'd refer you to him to talk about the details of the process and what it was that, from the chemist's point of view, was so critical.
But certainly, from the what the evidence in this case shows, the company themselves understood that they weren't looking at a full evaluation. That's what needs to be done. If you don't do a full evaluation, then you never know.
Q. Is it your opinion that any risk assessment that did not identify NDMA would have been

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inadequate?
A. I don't think I said that, no. I think what I said is, by not conducting an adequate risk assessment or a full risk assessment of their chemical process, that they have put patient health at risk because of their lack of understanding of what could occur and what impurities are in it now.
Q. What didn't they do, like what should they have done more that would have made it adequate, like what actual things?
MR. VAUGHN: Object to form.
A. I think I've already tried to answer that. I said it's my opinion they should have understood the potential for the different changes in their process where they went from a TIN process to the other, to introduce the nitrosamines, based upon doing a chemical process review. However, Dr. Hecht and the chemists in the case are the ones to talk to if you want to understand the chemistry and what was so important about this step or that step.
If you're asking me about a step in terms of a process they could have used, it's just understanding every input and every output and what are potential chemical reactions that could occur.
Q. You are offering an opinion that the

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risk assessment was not adequate, so I'm trying to understand what other things you believe, criticize Dr. Hecht, what you believe ZHP should have done to have an at quality risk assessment?
A. I think my opinion has been that the risk assessment wasn't adequate. It's based first on admissions by the company, when they say they didn't do a full review of their chemical process. That right there indicates to me that the risk assessment was not adequate. They are stipulating to that. Because part of that exchange, when you change a chemical process based upon the guidance from FDA and what in my experience companies do when they make a change to a chemical process, that they look at those potential reaction pathways.
I'm not an organic chemist by expertise. I have training in organic chemistry but I particularly am not doing organic chemistry in this case. That's the person that can describe for you the details in terms of how they should have looked at each of the inputs. It's not that there's a prescribed set of things people do, it's not like I can say to you that, "Go to this particular document and it will lay out from a regulatory perspective ten steps that must be done."

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Instead, what the guidance says is, you must understand, and understand the risks and look at your chemical process to identify things such as potential degradation products, potential byproducts. The fact that the company stipulates, the company being ZHP in this case, stipulates that they didn't do that, that's important to my opinion.
It's also important in this case, that companies like Teva/Torrent, and I describe this in my report as well, don't appear to have known what they should have done in terms of checking on what the ZHP was indeed telling them that they did or didn't do.
So regardless of whether or not ZHP has a duty, Torrent/Teva also have duties to make sure that they have validated their API suppliers, and understand that their API supplier is doing all the things they need to do in order to produce a quality product.
Q. Is it your opinion, every drug that contains an impurity is adulterated?
MR. VAUGHN: Object to form.
A. Depends. I can't say yes or no. It depends. It depends on the situation. So there are certain types of impurities that are allowed based

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upon the USP compendium. There are ones that have been identified and ones that are post-identification or accepted to be present in a product, and those evaluations are, you know -- know what those are. Right? We know what it is, impurity A, impurity B, impurity C, we see that occurring based upon the evaluation of regulatory agencies. Those are allowed or, based on the development of the product, and in the monogram, those are allowed.
But it just depends. If this is a new impurity, and an unknown impurity, something that the company gets because it's -- they have changed the process, then in those cases I would argue that you won't go -- those are the present impurities that could very well make it adulterated, but you have to figure it out. You have to know it's there to classify whether or not it is a genotoxin, for example.
Q. Can generic drug contain an impurity that's not contained in the RLD? And I think we can agree what the term "RLD" means, correct?
A. Reference Listed Drug, yes.
Q. If a generic drug contains an impurity that's not present in the RLD, is that generic drug

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adulterated?
A. Depends, same thing. Depends upon what it is, and what work that the company -- at the companies that are making the generic drug did in order to identify and understand their process. So it could be, yes.
Q. Is there an objective standard to know when a generic drug that contains an impurity not present in RLD is adulterated?
MR. VAUGHN: Object to form.
A. I don't think I understand your question, because are you asking me --
Q. Well, like you said it depends, so I'm trying to understand, is there like an objective standard that I can apply to know when a generic drug has an impurity, it's not in the RLD, what's the standard to determine whether it's adulterated in your opinion or not?
A. The standard of what is, is -- standard is what it is. For example, is it a genotoxin or not, is it a potent toxin or not? Understanding what the impurity is.
Are you asking me is there some level of impurity that -- well, USP monographs indicate potentially? Yes, some monographs will say that this

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impurity at this level is allowable. Is that what you're asking me? I can't tell you any particular one but you can go to the monogram for different drugs and they do list that.
Q. Are you talking about the USP monograph? At the time that these products were on the market, impurities under .1 did not have to be identified, is that correct?
MR. VAUGHN: Object to form.
A. As long as they are -- as long there was an understanding that they were not potent toxicants, or potent genotoxicants, yes, that is a standard that could have been applied, depending upon your process.
But again, this comes back to whether or not what you're doing is the process that's in the monograph. So when you change that process, which is what happened here, the RLD process was the TIN process, right? That's the one that Diovan, the RLD, was produced under, and that's what the monograph was set around.
In this particular case, the companies are using a different process to produce their product so just pointing back to the monograph and saying, "That is adequate," isn't adequate unless you know it's adequate, which means you need to

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understand your processes and what can potentially be produced.
Q. What is the difference between a genotoxin and a potent genotoxin? You've used both terms and I want to make sure I understand how you're differentiating them.
A. So "genotoxin" just means generally that the product, the chemical or the compound, or impurity, has the potential to damage or affect gene expression or cause mutations. There's a variety of types of endpoints. Genotoxicity just means that something produces an adverse effect through a mechanism related to DNA damage of some type.
A potent genotoxin, the reason I'm using it here, is because these compounds are that. These are ones that are known to be some of the most potent in terms of the propensity to, or their ability to product DNA damage.
Q. And is there literature that references to NDMA as a potent genotoxin? Where can I find that term in the literature?
A. I don't know if I cited that term. Let me see if I cited that in my report, to use that.
MS. MILLER: While you're looking, let's just mark Dr. Plunkett's report as Exhibit 1.

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EXH (Plunkett Exhibit 1, expert report of Laura M. Plunkett, Ph.D., DABT, dated 10/31/22, marked for identification, as of this date.)
(A pause in the proceedings.)
A. So my paragraph 43 is where I call them potent carcinogens. So potent carcinogens, I would argue, could also apply to potent genotoxins as well, could also be a potent genotoxin because we know that's the mechanism by which these compounds appear to act to produce cancer.
It's my statement and I think it's consistent with my review of the literature, so that's about the only thing I could answer for you right now based upon my report.
Q. You can't actually point to any literature that uses the word "potent genotoxin" with respect with respect to either NDMA or NDEA?
A. I know I've seen it before but I'd have to go back and find it because I don't cite to that in my report. So I can't answer that without going back and looking at my library of textbooks and other types of monographs and information. I believe you might see that described that way within either the IARC document, or within the WHO or the NCP or EPA documents that talk about the -- to find it, that I'd

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have to go look for you. I would argue that I don't believe there's any controversy that most toxicologists would call them potent genotoxins based on any data that exists.

Q. I can tell you that I've not seen that term --

MR. VAUGHN: Object, argumentative.

Q. -- I'm wondering if you have actually seen that term anywhere in the literature.

A. I believe I have. But again, regardless of whether I have or not, as a toxicologist, the behavior of NDMA and NDEA in particular, in animal studies, for example, and also in in vitro studies for genotoxicity indicate that it's a potent compound to produce the effects that it does.

And so I'm calling it either a potent carcinogen, I would call it potent toxicant, I would also call it a potent genotoxin because it is one that reliably, over and over again, in fact, with the animal studies, what's interesting as I described in paragraph 43, there's actually a study showing that single doses prenatally have been shown to be carcinogenic in animals once they are born, a pretty potent effect.

Q. Can you give me an example of a

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genotoxin that's not potent?

A. Lead is an example of something that's not a potent genotoxin. It has genotoxicity effects in some assays but not in all. "Potent" in genotoxicity, typically as a toxicologist, I would use that word because regardless of the assay you test it in and how many times you test it over and over again, it produces genotoxic effect across the range of exposure levels in cells with and without activation.

Q. Do you have an opinion as to what dose of NDMA or NDEA is necessary to render those -- to render them carcinogenic?

MR. VAUGHN: Object to form.

A. That's beyond the scope of what I did. I told you that earlier. However, there are others who have addressed that. And in this litigation, and I would also say there are potentially, you can go back and look at the IARC monograph where it goes through all the studies and exposure levels and what the extrapolated cancer risk would be based on different exposure levels in animal studies. So that you can get to.

You can get to where this -- what exposure level increases cancer above the one in a

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million or one in a hundred thousand risk level. You can do that based on animal data.

Q. Are NDMA and NDEA found in foods?

A. Are you asking me are they found in any food at all? They can be. Depends on the conditions under which the, for example, maybe the food is cooked, that has some effect on that but there is in background level of exposure, yes.

Q. Have those foods been banned by the FDA?

MR. VAUGHN: Object to form.

A. That's beyond the scope of the work that I did, to look to see if that's true for any -- so I would say to you, I don't have an opinion one way or the other. I'm not aware of some of those foods being banned, no, I'm not aware of that. But it's a very different thing to talk about something that can be controlled and something that can't be controlled. So talking about exposures in food that may be there and are things that it's very difficult to control, whereas we know that this drug can be made without it.

So there's a different calculus when you talk about looking at risks posed by food versus risk posed by a drug where we know you can make it without them there.

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Q. If a family member had come to you and said, "I just found out there's NDMA in one of the foods I like, herring, I like herring and there's NDMA in herring," would you have told them to stop eating herring?

MR. VAUGHN: Object to form.

A. I don't think I would have. I would have told them that I'd have to do an investigation because it really depends on what people are eating, how their foods are prepared, those are all important for potence of that. Foods can have things in them that are harmful, but typically the things that foods have in them that are harmful are not at the levels that we're talking about in this case, for this particular impurities. That could have occurred at many, many orders of magnitude higher than the levels that may be found in food.

Q. Have you told any members of your family or any friends to stop eating cured meats because they contain nitrosamines?

A. No, I've never been asked that.

Q. Have you told any members of your family or any friends to stop eating bacon because it contains nitrosamines?

MR. VAUGHN: Objection, foundation.

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A. No. I've told people that they can be harmful in terms of heart disease issues. People have asked me that before. So for example, myself, I try to eat less red meat but it just has to do with, I'm in my 60s, I don't know, I'd like to remain healthier as I go forward.
Q. Have you ever suggested to any family or friends that they stop eating any fermented foods because they contain nitrosamines?
MR. VAUGHN: Objection, foundation.
A. No one has ever asked me that question. So --
Q. Have you ever offered, unsolicited, sua sponte, suggested to any of your loved ones to stop having cured meat or bacon, or fermented foods because of the nitrosamine content?
MR. VAUGHN: Objection, foundation.
A. Not solely based on that, no, as I already answered. Typically the issue is whether or not certain kinds of foods that you're talking about, like cured meats, things like that, my issue is, as I do believe that it's the higher -- meat generally is better for you to some extent, but that's just because of me and I have family risk factors for high cholesterol levels and things like that.

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So it's -- it's more complex than just talking about -- and no one has ever asked me that question so I haven't --
Q. Are the nitrosamines in cured meat, bacon, and fermented foods potent genotoxins?
MR. VAUGHN: Objection, foundation.
A. Well, I'm not sure which ones you're referring to, because there's a variety of nitrosamines. Some are more potent than others. So NDMA and NDEA are some of the more potent ones. So the issue, this is the issue for food.
So food can have many different N-nitroso compounds potentially in them, some of which actually have been shown to carry a different level of risk than others. And at issue in this case, these particular ones, NDMA and NDEA, are ones that are labeled as probably human carcinogens, specifically because the data has been so consistent showing that they are indeed able to, or have been associated with, I guess, in the animal studies, cancer repeatedly over and over again.
There is a mechanism that has been linked to genotoxicity. And again, the exposure levels have been across the exposure levels. It's not like you have to have a very high level of

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exposure producing cytotoxicity before you get a cancer or a genotoxic effect.
Those are kind of the kinds of assessments that you can do in order to use adjectives like "potent" or "not potent" when you're talking about a compound.
Q. Fair enough, so let's just focus on NDMA. Is the NDMA that's found in cured meat a potent genotoxin?
MR. VAUGHN: Objection, foundation.
A. NDMA is a potent genotoxin by itself. That's the opinion that I have. So regardless of where you find it, it's a potent genotoxin. However, like anything else that you talk about, you have to consider whether or not, when you have a situation where you can't control for it, or you can control for it, that weighs into your calculation over how you would handle and respond to the situation.
So in this case, we know we can make the compound without the NDMA. That's really important. And that's why in this particular case, I have formed the opinions I have related to the responsibility of the company, what should or shouldn't be done. This thing can be made without it, it should be made without it. It is not meant to be there.

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Q. Is cured meat containing NDMA a potent genotoxin?
A. It's not the cured meat. I already answered this question. You talk about what a compound is and then from there, you have to do an assessment of where it is, how it got there, should it be there, can it be controlled or not.
I'm not arguing with you, but I'm aware that nitrosamines can occur in food. I've already answered that question. It can. But there's an important contextual discussion that's different for the risk in food versus the risk in these products, and so I would argue to you, based on my experience and training, that when you have a compound like this, a potent genotoxin in a drug product and you can make that drug without it, just as FDA has said, you should be making it without it. You should prevent it or remove it. It's unacceptable for it to be there.
And that's a different assessment than you would do if you were talking and considering issues related to food safety.
Q. Is cured meat with NDMA carcinogenic?
A. It's the same answer. I wouldn't answer that cured meat is carcinogenic, I would tell you

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that NDMA is carcinogenic and as a result of that, you would look at the safety of the food as it would or wouldn't exist related to the presence of things such as nitrosamines in it. And it really -- it's -- I'm not trying to be a maven, I'm just telling you it's different -- you're talking apples and oranges when you talk about food safety assessment versus prescription drug assessment for presence of an impurity.

Q. Do you believe that cured meat with NDMA should be banned?

A. I have -- that's beyond the scope of any opinion. I haven't formed that opinion, no.

Q. How about smoked and salted fish that contains NDMA, do you think it should be banned?

MR. VAUGHN: Objection, foundation, scope, relevancy.

A. I have not formed opinions about banning any particular food that would or wouldn't contain any nitrosamines at this point in time.

Q. Would you advise a family member or friend to stop eating smoked salmon if that smoked salmon contains NDMA?

MR. VAUGHN: Objection, relevance.

A. I don't know. It depends upon the

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situation what you're talking about. What nitrosamines -- what -- what are you talking about? Was it something that has -- that can't be controlled for, they eat it once a week, they eat it every day? I mean, there's all kinds of things.

Again, food safety assessment is different than what we're doing here. I have not done those assessments and I have not advised anyone based upon that other than generally, like I told you, that I think red meat can be a problem for heart disease, so I choose to eat less of that.

Q. We we're talking about fish right now, not red meat, right?

MR. VAUGHN: Objection, argumentative.

Q. My example was smoked salmon. So my question for you is, you said it depends if they eat it once a week or not. Is that because the dose of a carcinogen is relevant to safety?

MR. VAUGHN: Object to form.

A. For food safety, it's not the dose, it's exposure level. So the exposure level is relevant to food safety assessment. It's understanding what are the ranges of a -- what is the range of levels that could or couldn't occur in food, but you do look at, you make for a population assessment -- which is what

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you're asking me, I think, that's the only thing that makes sense -- a population of people that are eating salted fish or smoked fish. And we know that there are certain kinds of background levels and certain kinds of compounds that are in those particular products. Is there a level at which it could be adjusted and said to be safe? I have not done those assessments. And I think it would be highly dependent upon a lot of things. What particular nitrosamines you're detecting, how many of them, whether or not they occur at all times, whether it's something that could be also controlled by the way you smoke the meat, for example, or smoke the fish. Those are all relevant to that.

I'm not aware of any -- of FDA banning, for example, smoked fish. I'm not aware of those kind of things happening, for those kind of products. But that doesn't mean, like anything else, that you can't go to the FDA website, which I know you can, where they have discussions of nitrosamines in food. So you can see that there are discussions about certain kinds of foods having higher levels than others in those kinds of things.

Q. Does your level of exposure to NDMA affect whether it increases your risk of cancer?

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A. As a regulatory consultant, I am not making an -- the opinion of a specific increased risk level, no. So in my report based on my role in this litigation, no, I have not formed that opinion, it has to be at a certain level or not. What my opinion is, as I've already told you, is that it's an impurity that is not acceptable, not supposed to be there, so any NDMA makes this product unacceptable and increases your risk.

Q. At the beginning of your deposition you said you were here both as a toxicologist and as a regulatory expert. I'm asking this question as a toxicologist. My question as a toxicologist is, does the level which you're exposed to NDMA affect whether or not it increases your risk of cancer?

MR. VAUGHN: Objection, scope.

A. It's beyond what I was asked to do in this case. So from a general -- from a general discussion of toxicology, I've already described for you that in the terms of cancer risk assessment for these kinds of compounds, the assumption is that there is no safe level. In other words -- and then what you have to do instead is balance what you assume was exposure would be and talk about what is* that increased cancer risk level, are you willing to

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accept one cancer in a million or one in a hundred thousand or one in ten thousand, and those are decisions that are made by regulatory bodies or scientists in order to describe the risk.

But that's why cancer is not described as an ADI. It's not like you can go and say, "This level of exposure, if you're exposed to this level there is absolutely no risk." That doesn't exist for these kinds of compounds.

Q. Based on a safe level exposure to NDMA, would that apply to foods as well as medications?

MR. VAUGHN: Objection, scope.

A. The issue of -- the issue of NDMA generally, and doing a risk assessment would be that there is an understanding that there -- that cancer -- cancer risk and safety assessment is done differently than it is for a non-cancer event.

As a result, if you're going to do a food safety assessment, if you're going to do a drug safety assessment in this case, or a risk assessment, you have to somehow go through the process of determining how -- what level of risk is acceptable to you as a regulator. And that's what the regulator would do, or you as a toxicologist.

It was beyond the scope of what I did to

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do any specific assessments for any specific individuals in this particular case based on any particular exposure pattern.

Instead, what I'm telling you as a toxicologist is, maybe the best way to describe it is, there's two ways toxicology can describe cancer. It can describe it based on whether or not generally it poses a hazard of cancer. If there's an increased risk, does it exist or not?

Yes, I'm saying it does exist, and then after that, in order to qualify the risk, you as a toxicologist could look for the specific set of facts. That was beyond the scope of what I did but there are others in this litigation who are doing that.

Q. I don't really think that answered my question. It was actually much simpler. My simple question was, you said there's no safe level of exposure to NDMA in medication. Is there a safe level of exposure to NDMA in food?

MR. VAUGHN: Objection --

A. I don't think that is what I said. I'd have to go back and look at the record to see what you're saying I said. What I'm saying to you is, NDMA is carcinogenic based upon the methods that we

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use as toxicologists to look at cancer risk. That methodology, it is premised only the basis of what is the risk that would be acceptable or not acceptable. So you would set an exposure level which you're willing to live with, based upon whether you are okay with one in ten thousand, one in a hundred thousand, one in a million increase in cancer risk.

However, on -- that's for population. For any one individual, the answer could be very different. And that's because each individual you might look at might have other susceptibilities, other types of risk factors that would tell you that you would want to have a different paradigm or a different metric for determining whether or not it's likely that cancer would develop because, don't forget, that's a lot of what we're doing here.

And what I was explaining to you is, to try to give you an understanding, it's very different than the way we look at non-cancer risk assessment, where we can identify or we assume we can identify a level with no risk.

MS. MILLER: Let's take a break.

VIDEOGRAPHER: Going off the record. The time is 10:49 a.m. This is the end of media unit 1.

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(Recess taken.)

VIDEOGRAPHER: We're back on the record. The time is 11:08 a.m. This is the beginning of media unit 2.

MS. MILLER: Thank you. I'm going to mark as Exhibit 2 a July 13, 2018 FDA press release.

EXH (Plunkett Exhibit 2, FDA press release dated 7/13/18, marked for identification, as of this date.)

THE WITNESS: Are you putting these in the Exhibit Share file or -- because I know that if I need to look at more than you put on the screen I can do that?

MS. MILLER: I think we can give you control, right?

MR. VAUGHN: As the defending attorney, I need to be able to view the full exhibit.

THE WITNESS: So you're putting it in the share?

MS. MILLER: We're doing both. We're putting it on the screen and at the same time Alex is putting it into whatever the appropriate protocol is.

EXAMINATION (Cont'd.)

BY MS. MILLER:

Q. Dr. Plunkett, are you familiar with this

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press release?
A. Yes, it's been a while since I've looked at this one but yes, I am familiar with it.
Q. If we can look at the bottom sentence on the screen, it says the presence of NDMA was unexpected, do you see that?
A. I do.
Q. Do you agree with the FDA that the presence of NDMA was unexpected?
A. If by "unexpected," you were defining that as something that was not part of the monograph for the drug and also was something that they had not seen before, that unexpected I would agree with. But I don't believe if you're going to use the -- a definition that it couldn't have been known, I disagree with that.
Q. Do you know what the FDA meant when it said the presence of NDMA was unexpected?
A. I can only read that based upon the general English understanding of "unexpected" --
Q. And what is the general English understanding of the the word "unexpected"?
A. Something -- I would say something that you had not seen before.
Q. Is that a dictionary definition of

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"unexpected," something you had not seen before?
A. I don't know.
MR. VAUGHN: Object to form.
A. I mean, there's multiple definitions, I'm sure in the general dictionary. As a regulatory expert, that's how I define the word "unexpected" based on the general imagery.
Q. Is "unexpected" a regulatory term?
A. Well, I've seen it used in regulatory -- this is a regulatory document. It's something, FDA, the regulatory agency, was writing it, so that's how I am defining it based upon my experience.
Q. And in your experience, does the term "unexpected" have a different meaning in the regulatory context from the regular speech casual way in which the term is used?
MR. VAUGHN: Object to form.
A. Highly dependent upon the speaker, in the context of a sentence and the information there. But in my view, "Unexpected" here is telling me that the presence of NDMA is something that they did not know was there, "They" being the FDA. It wasn't part of the monograph, it wasn't something that they had been told by somebody.
Q. Is it your understanding that the word

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"unexpected" here is used in a regulatory context rather than in the general understanding of the word "unexpected"? That's my question.
MR. VAUGHN: Object to form.
A. I would say, since this was written by a regulatory agency, that they are calling it as a general English meaning of "unexpected" because this is a press release, that for consumers to view as well, but also understanding that as a regulatory agency, they will choose their words based upon their role, their duty and their responsibility.
Q. Let's move on to Exhibit 3. I'm marking as Exhibit 3, an August 30, 2018 FDA statement.
EXH (Plunkett Exhibit 3, FDA statement dated 8/30/18, marked for identification, as of this date.)
MR. VAUGHN: Jessica, I'm not seeing the exhibits in the share folder.
MS. MILLER: Alex is going to figure that out. Why don't we go off the record and figure out for a minute, just to figure out how to make this exhibit process more efficient.
VIDEOGRAPHER: Okay, going off the record. The time is 11:14 a.m.
(Discussion off the record.)
VIDEOGRAPHER: We're back on the record.

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The time is 11:20 a.m.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. I think we were at Exhibit 3, and Alex is putting it on the screen and it's an August 30th, 2018 FDA statement. Oh, just a moment, just to go back to Exhibit 2, the July 13th, 2018 press release, do you recall, Dr. Plunkett, if you mentioned that press release and the statement about the presence of NDMA being unexpected in your report?
A. Oh, the press release is the only -- I listed the entire, all of the FDA statements, all there. I don't know that I mentioned that specifically, so I can't -- I don't believe I did, probably.
Q. Okay. Let's move on to this Exhibit 3. Exhibit 3 again, as I said, is the August 30th, 2018 statement. This is called an FDA statement, not a press release. Dr. Plunkett, do you recall if you quoted this document in your report?
A. All my reliance material, I know I quoted the follow-up, which was an update, in 2019. But I don't know if this one is there. You want me to look? I can look real quick.
Q. If you don't know, I don't want to take

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the time for you to look.
MR. VAUGHN: Dr. Plunkett, take time to scroll through the document, so you know if you actually quoted it or not.
(A pause in the proceedings.)
Q. If we could turn to page 3 of this document, if you could look at the third paragraph that begins, "In St. Louis"?
A. Yes, could you make it a little bit bigger? Just a little bit bigger, not a lot maybe. There you go, sorry. Are you talking about the highlighted box --
Q. No, I don't know why those are highlighted. Those were not done by us.
A. Okay. So starting --
MR. VAUGHN: Was that highlighted on the FDA's website?
MS. MILLER: I don't think these are highlights.
MR. VAUGHN: Were these boxes on the FDA website?
MS. MILLER: This is how it printed. If you look, every time it's highlighted there's a hyperlink, Brett. We didn't manipulate the document in any way, if that is what you're asking.

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MR. VAUGHN: Okay.
Q. Okay. So my question is, if you read the third paragraph it states, "In St. Louis, FDA maintains the most advanced pharmaceutical laboratory of any regulatory agency in the world. As soon as we were aware of the NDMA impurity in certain valsartan drugs, we began collecting samples of all valsartan API and products marketed in the U.S. At the same time, our scientists began developing a test to detect and and quantify NDMA in Valsartan API. NDMA's properties make it difficult to find."
Do you see that?
A. I see that text, yes.
Q. So the FDA here is stating that it has one of the most, or almost most advanced pharmaceutical laboratory of any regulatory agency in the world, correct?
A. That is what they claim, yes.
Q. And they state that they had a challenge in developing a test of quantifying DMA, correct?
MR. VAUGHN: Object to form.
A. No, I don't think they had a challenge. I think they pointed out that NDMA itself has properties that can make it difficult to find, but didn't say that it was necessarily a huge challenge

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that was unsurmountable --
Q. Does FDA say NDMA's properties can make it difficult to find, or does it say NDMA's properties make it difficult to find?
A. The text says, "NDMA's properties make it difficult to find."
Q. Do you agree with that statement?
A. I'm not a chemist so that would -- I would defer that to Dr. Hecht.
Q. Do you know why NDMA's properties make it difficult to find?
A. The same answer. It's my understanding others can answer these questions for you as chemists, and I'm not the chemist in the case so I would defer to Dr. Hecht.
Q. Okay. And if we could continue, if FDA says, "CDER scientists have now developed" -- I'm sorry, let me begin at the beginning of the sentence, "To determine if" --
A. Could you -- stop.
MS. MILLER: -- stop moving it around. You're just making us dizzy.
Q. It says, "To determine if Valsartan products do contain this impurity, CDER's scientists have now developed the gas chromatography mass

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spectrometry headspace testing method." Do you see that sentence?
A. I see that sentence.
Q. So the FDA had to develop a new test in order to determine whether the Valsartan products contained NDMA?
MR. VAUGHN: Objection, form, scope. Foundation.
A. So that's beyond the opinions that I have developed. Again, I know that this is talked about in the other reports by other experts in this case. They did state that they developed a method, yes. That I agree, that's stated in the sentence. It has nothing to do with, in my view, any kind of judgement about the difficulty or the -- or the fact that they often develop tests. I mean, FDA develops tests all the time, and --
Q. Do you know why FDA had to develop a new test?
MR. VAUGHN: Object to form.
A. I can't get into FDA's mind to know that. I can't tell you. I wasn't there to have a discussion with any particular chemist on why they did it. I know that the overall issue in the case, why it was needed, was because there were these

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impurities being found and they didn't understand the extent of the problem.
Q. Do you know whether FDA had any prior tests that would have identified NDMA?
A. That's beyond the scope of what I did. I would defer you to the other experts in the case that are handling this area.
Q. If we could move on to page 4, first paragraph. "We believe that these risks are introduced through a specific sequence of steps in the manufacturing process, where certain chemical reactions are needed to form the active ingredient." Do you see that?
A. I see that, yes.
Q. And the next sentence says, "Before we undertook this analysis, neither regulators nor industry fully understood how NDMA could form during this process," do you see this sentence?
A. I see that sentence.
Q. Did you fully understand in 2018 how NDMA could form during the process through which Valsartan was manufactured?
MR. VAUGHN: Object to form.
A. Well, that wasn't my job. That was the job of the companies making the product, to fully

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understand the chemical process.
Q. Do you disagree with FDA's statement that neither regulators nor industry fully understood how NDMA could form?
MR. VAUGHN: Object to form.
A. I neither agree nor disagree with that statement. It is a statement, is what it is. But I would point to the fact that it's the job of the industry to fully understand their chemical processes and the ways that potentially harmful compounds can be formed during those processes, and this is what the company has stipulated they did not do.
Q. Is it possible for a company to perform an adequate risk assessment and still not identify certain risks that are hard to find?
MR. VAUGHN: Object to form.
A. I don't know, that's a -- it's would highly depend on the situation, the specific compounds, specific process, so I don't think there's a yes or no answer to that.
Q. Did you discuss this statement in your report?
MR. VAUGHN: Object to form.
A. I don't cite this statement, but I do discuss the issue of the need to understand the

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process, and whose responsibility it was. Again, it's not FDA's responsibility to understand. It's the company's responsibility to understand, and then provide that information to the regulatory agency.
Q. I just was asking if you used this quote in your report.
A. I started -- I usually start, like I did, I start out I said, I didn't cite this but, and then I gave you an explanation. So I do believe I answered your question in the first part of my answer.
Q. Turning now to page 5. In the middle of paragraph 2, the FDA states, "Was not anticipated that NDMA would occur at these levels in the manufacturing of the Valsartan API." Do you see that?
A. The sentence that started with, "Because," that's where you are?
Q. Correct.
A. I see that clause, yes.
Q. Do you agree with the FDA that it was not anticipated that NDMA would occur at these levels in the manufacturing of the Valsartan API?
A. I haven't formed an opinion on that one way or the other. That was beyond the scope of my

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work.
Q. And then FDA says, "Because it was not anticipated that NDMA would occur at these levels in the manufacturing of Valsartan API, manufacturers would not have been testing for it."
Do you agree that manufacturers would not have been testing for NDMA because it was not anticipated that it would occur at these levels in the manufacture of Valsartan API?
MR. VAUGHN: Object to form, foundation.
A. So the same answer. I don't agree or disagree. This is beyond the scope of my work.
Q. Is it beyond the scope of your opinions whether it was anticipated that NDMA would occur at these levels in the manufacture of Valsartan API?
MR. VAUGHN: Object to form.
A. It's beyond the scope of my work from the aspect of the chemistry of the reactions or the description of the foreseeability based upon an analysis of chemical process, which is what the chemist has done in this particular case.
But it is my opinion that, based upon the company's own admission that they didn't do a full analysis, that that's a -- that's a particularly important fact in this case. So in other words, if

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you don't do something, there's no way you'll ever be able to figure out whether it could or couldn't be there. So it would be the issue of not doing the full chemical analysis is the important first step.

Q. Do you consider yourself to have the expertise to review the risk analysis undertaken by ZHP, and independently determine whether or not it was adequate?

MR. VAUGHN: Object to form.

A. I haven't done that full analysis of all the chemical reactions, no. That was beyond the scope of what the chemist did. However, my opinion where I say that the risk assessment was inadequate was based upon the company's own admissions that they didn't do a full chemical analysis in their process, which is what is required in order to ensure that your product meets GMPs consistent with the GMP process, and also can be -- you could have some level of certainty that you have attempted to address all the safety issues that could be raised by the product.

Q. Did you quote the sentence in your report that it was not anticipated that NDMA would occur at these levels in the manufacture of Valsartan API -- it's the same sentence. Did you quote this

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sentence that we've been discussing in your report?

A. I'm looking because I thought I called it -- some of language is very similar to language that shows up in a later document that I do quote from. I'm looking to see.

I quote Dr. Gottlieb. This is Dr. Gottlieb's statement. He had one, an update and he used some of the same language, and I'm looking to see what I quoted, so just give me a second.

MR. VAUGHN: Take your time, Dr. Plunkett.

(A pause in the proceedings.)

A. I don't quote that specific sentence, no. But I certainly cite to a document that has this and many other sentences in it.

Q. Moving on to Exhibit 4.

EXH (Plunkett Exhibit 4, FDA statement dated 1/5/19 from Scott Gottlieb, M.D., marked for identification, as of this date.)

MS. MILLER: Exhibit 4 is a January 5, 2019 FDA statement by Dr. Gottlieb.

Q. I'm guessing that's the other Gottlieb statement you were referring to.

MS. MILLER: Alex, do you have that up on the screens?

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Q. Let's go to page 4. Page 4 of this --

A. One second, could you go to the front page again for me, the first page? Yes, this is the one that I think I had some of the same language as the document they sent over that has other issues, that it discusses as well.

Q. If we could turn to page 4, Dr. Gottlieb states, "One challenge we've faced is that NDMA's properties make it hard to detect with standard laboratory testing," do you see that? It's the first sentence of the second paragraph.

MR. VAUGHN: Object to foundation.

Q. "One challenge we've faced is that NDMA's properties make it hard to detect in standard laboratory testing"?

A. Well, you have to read the rest of the sentence because he's describing what he means by "standard lab testing," the kind of testing results that were reviewed during the surveilling section.

Q. Do you agree with that statement?

A. I don't, just as I said before, I wouldn't say I agree or disagree. It is FDA's statement and again, this issue is beyond the scope of my work. I would defer to the chemists in the case who address these specific issues.

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Q. And when you say it's beyond the scope of your work, is that because you're not -- you don't have the credentials and expertise to assess the adequacy on your own of laboratory testing for chemical compounds?

MR. VAUGHN: Object to form.

A. No. That's not the necessarily true. There are cases that I -- there are things I have done in my training and experience in the laboratory where I've developed testing methods. I'm just saying to you that this is is not something I have done in this case, and others have.

So again, I am not providing testimony on this particular specific issue about standard laboratory testing and the difficulty with it, or whether it was or wasn't standard. I would argue that GCMS is a standard test that I see used every day in laboratories around the world. So if the issue is, is GCMS a standard lab test, it is.

However, there's a separate issue here which is that they are then saying the kind of testing that they reviewed during their surveillance inspection were the kind of testing that the company who sent in the ANDA, or the Drug Master File, may have described.

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Q. Do you have a degree in organic chemistry?
A. No, but I have training in organic chemistry as part of my pharmacology and toxicology background. I took four different courses in organic chemistry over the years.
Q. How many years ago was that?
A. In my training, so the last course that I took would have been in the 1980s.
Q. So that's forty years ago?
A. You're making me sound really old, but that's true, yes. That's right.
Q. Have you ever conducted testing for nitrosamines?
A. I don't know. I'd have to go back and think about that. It's possible in my laboratory days I did, but I don't recall that.
Q. When would that have been?
A. Before 1989.
Q. So in the last forty years have you conducted any testing for nitrosamines?
A. Last thirty years I would say no, I have not. I don't know about forty yet. The last thirty I have not. But I can't recall.
Q. Have you ever developed any laboratory

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testing that was intended to identify the presence of nitrosamines?
A. I can't answer that without going back to looking at the kind of work -- I did develop different kinds of methods where it's possible that the N-nitroso group was a way to test this part of the separation procedure. But off the top of my head, I can't think of a project where that was the target of my work or the focus of my work, no.
Q. Do you know sitting here today whether it is easy or hard to develop laboratory testing to detect NDMA?
MR. VAUGHN: Object to form.
A. I haven't formed an opinion one way or the other. And I would say that statement would probably be highly dependent upon one person's opinion based upon what they think is hard and what they think is easy, so -- but I have not formed an opinion on that issue one way or the other.
Q. Do you know how the FDA was using the term "hard" in this sentence that we've been discussing?
A. I can only define it based upon standard English as "hard"; in other words, it required some effort.

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Q. How much effort?
A. That's subjective. That's subjective, and I think you'd have to -- you'd have to ask each individual, which is why I would defer you to the chemists. The chemist can speak with experience based on their work in developing methods that are similar, whether or not it's hard or easy.
I would say to you, GCMS is the standard laboratory tool and if that's the method they used, I wouldn't have expected it to be "hard" in terms of the use of a method. But whether or not they had other things they did, I would defer to the chemists.
Q. As a regulatory expert, are you questioning FDA's use of the word "hard" here?
A. No, I haven't questioned their use of the word "hard." This is FDA's statement.
Q. Are you offering an opinion that FDA's statement that it was hard is erroneous?
A. I have not developed that opinion at this point in time, no.
Q. Does FDA employ chemists?
A. Yes. Well, again, the duty for all of this is not FDA's. The duty of this is the company making the product.
Q. I understand. But my question is, does

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FDA employ organic chemists?
A. I answered that and said yes, and then I said yes.
Q. My first question was chemists. My second question was organic chemists.
MR. VAUGHN: Asked and answered.
A. I apologize. I assumed that chemists included in -- "chemists" in my view, when I'm answering that question, is encompassing chemists of all different kinds.
Q. Based on your understanding of how the FDA works, would there have been organic chemists involved in the efforts to create this testing that the FDA define as hard?
MR. VAUGHN: Objection, speculation.
A. I don't know. I'd have to go back and see if I could find the names of the individuals and what their background was. So I can't answer that without looking. I don't know.
Q. Do you know whether the FDA employs organic chemists in St. Louis in the most advanced pharmaceutical laboratory of any regulatory agency in the world?
MR. VAUGHN: Objection, form.
A. I can't answer that without looking. I

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would assume they do, but I don't know.
Q. Do you know whether the FDA has a division of chemistry that reviews drug master files?
A. They have a division of chemistry and one of the things they can do is review drug master files. But they don't do it except in certain circumstances.
Q. Do you know whether anyone from the FDA division of chemistry ever reviewed any of ZHP's drug master files?
A. I don't know that I can answer that without looking at documents. I don't recall if there's a document that indicates that. So I can't answer that off the top of my head.
Q. Okay.
MS. MILLER: Let's go off the record.
(Discussion off the record.)
VIDEOGRAPHER: Going off the record. The time is 11:42 a.m.
(Discussion off the record.)
(Recess taken.)
VIDEOGRAPHER: We are back on the record. The time is 12:01 p.m.
(Continued on following page.)

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EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. Earlier today we marked your expert report, Dr. Plunkett, as Exhibit 1. I'm guessing you have a copy of it in front of you, is that correct?
A. I do.
Q. Do you have anything else in front of you today?
A. I have only the notice of deposition document, and I printed out the 2019 letter just because I had looked at that yesterday, and I have two other documents I printed out just because they are in my report. One was the '99 "Guidance For Industry on Purity," because I cite that in my report, and I also printed out something I cited in my report from the NDMA website, "Q&A on CGMP Practice."
Q. Sounds good. And I assume you don't have any other programs open on your computer?
A. No. -- well, I was going to ask this question. So now that you're sharing the screen, if I want to go look at a document, I don't know how to do that because you take up all my screen. So if it gets to that, I'm going to have to ask if I want to look at it separately. But this one I have. I have

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your -- my report, if you want to talk about that.
Q. I'm not using a lot of documents today, so that will be okay. Dr. Plunkett, can you please turn to page 28 of your report. Do you see these images here?
A. Yes, I do.
Q. Where did you get these images from?
A. These came from Casarett images -- actually, here, I have footnotes. Images -- I have footnote 35, tells you there. So they are from the web. The Internet, you can search the Internet for chemical structures, rather than drawing them yourself, so that's what I did.
Q. And what is this website?
A. Well, I -- you need to go to it, it's a website that had -- when I Googled structures, chemical structure, NDMA, NDEA, nitrosamines, this is the website that came up and I checked those, obviously. I'm aware of the general structure of the nitrosamine, the first core structure. You can actually find that in Casarett & Doull as well, which is -- which is a textbook that I cite for, and then these others came from the same site, but I -- I'm aware of what N-dimethyl -- N-dimethyl looks like, and -- and N-diethyl looks like, so, yeah, I'm enough

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of a chemist that I could tell you these are correct.
Q. What is shionogi-ph.co?
A. That's the website. It's probably a chemical manufacturer website. And you want me to go look, I'd have to go look and I can't do that with you having the screen taking up my entire -- but you should be able to do that.
Q. I'm just asking if you know what it is.
A. It's a website that I believe has chemical structure information, and it may be a chemical manufacturer, someone who sells these compounds, but I'm not sure. I'd have to go back and look.
Q. Okay. And then what is footnote 36 representing? In other words, did these images come from footnote 35 or footnote 36?
A. Oh, okay. The core structure comes from 36 and NDMA and NDEA come from 35.
Q. Okay, that was not clear. And do you know what "eurofins" --
A. Yes, Eurofins is a testing laboratory that has international -- offices around the world, they also do regulatory consulting. I use them with my clients in different regulatory space to handle work and develop analytical methods at times.

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Q. And why do both of these websites end in .jp?
MR. VAUGHN: Object to form. Calls for speculation.
A. I don't know. I can't answer.
Q. Okay.
EXH (Plunkett Exhibit 5, Boerner article from Chemical and Engineering News dated 4/20/20, marked for identification, as of this date.)
MS. MILLER: I'd like to introduce as Exhibit 5 an article by -- I'm really just butchering her name -- Leigh Kreitsch Boerner. We're going to show you the spelling. Alex is putting it up on the screen right now.
This is an article from Chemical and Engineering News. Have you ever heard of Chemical and Engineering News before --
MR. VAUGHN: Give me just one second, Jessica, unless you're finally --
Q. Before we introduce the document, while he's looking for it, I'm just asking if you have heard --
MR. VAUGHN: Understood --
MS. MILLER: I won't ask anything about the document, obviously.

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MR. VAUGHN: Fine.
A. If the question is have I ever heard of it, yes. They are a trade press type publication.
Q. And do you regularly read this publication?
MR. VAUGHN: Object to form.
A. I don't reg -- I don't seek it out on a monthly basis, but I have read it before when I have had an issue. Sometimes it's referred to in other places that I'm reviewing. So for example, I might be looking at an article that's put out by RAPS on their website, the Regulatory Affairs Professional Society, and then might refer back, so just depends.
Q. And have you seen this article before?
A. No, I have not seen this article. So if you're going to ask me specific questions, I would need to read through it.
Q. Okay. I am going to ask you specific questions. My understanding is that under the CMO in this case, if you're going to read an article, we're allowed to go off the record. So let's go off the record for you to read it.
A. So before you go -- I need to know how to get to it, because I don't seem to be able to get to my screen.

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MS. MILLER: Let's figure that out once we go off the record.
VIDEOGRAPHER: Okay, going off the record. The time is 12:07 p.m.
(Discussion off the record.)
VIDEOGRAPHER: We're back on the record. The time is 12:18 p.m.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. Dr. Plunkett, are you familiar with an organization called Health Canada?
A. Yes.
Q. What is Health Canada?
A. Health Canada is essentially the paid equivalent of the FDA but it's not exactly the same. Health Canada actually does assessments, health assessments for products outside of some of the FDA regulated products as well.
Q. Have you ever relied on Health Canada in forming your opinions in any litigation?
A. Typically, I'm not allowed to in the U.S. They will mention the U.S. regulatory agencies, but I have generally in my work relied on Health Canada and certainly, I have done work for clients related to submissions of Health Canada.

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Q. Have you relied on Health Canada in forming any of your opinions in the talc litigation?
A. Yes, because there was a separate report for Canada healthcare, so I'm working on the talc litigation that is related to claims in Canada and Health Canada.
Q. And did you give credence in that litigation to the Health Canada report?
A. I don't know how you define "credence," but the if you mean did I refer to it? Yes. And I certainly did rely upon some of the documents and the reviews that Health Canada did, yes.
And I'm sorry, Ms. Miller, you were asking me about the talc litigation, correct?
Q. Correct.
A. Yes. So the answer to the last question about reliance had to do with the talc litigation.
Q. Okay.
A. That's fine.
Q. And do you consider Health Canada to be a reputable organization?
MR. VAUGHN: Object to form.
A. Well, it certainly -- I would say it's one of the regulatory bodies that I have seen applies good standard scientific practice, yes. But they

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have different regulations so the context of the work they do is a bit different from the FDA. And so that's important to recognize when you look at what Health Canada does and why they make certain decisions. They have different laws, in other words.

Q. If you turn to page 3 of this article -- I'm sorry, of this -- yeah, so if we could turn to page 3 of this article, who publishes Chemical and Engineering News?

A. I don't know who. I just know it as a trade press journal that I have seen before.

Q. Have you heard of the American Chemical Society?

A. Yes, I have.

Q. What is that?

A. It's a scientific organization that's related to the chemical industry and chemists.

Q. Does the American Chemical Society publish this journal?

A. I said I didn't know. I'd have to look. I don't know.

Q. Do you know whether the reporters and editors in this journal have advanced degrees in chemistry?

MR. VAUGHN: Objection, foundation.

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A. Same answer. I'd have to look. I don't know.

Q. If you could turn to page 3, this article says, "NDMA is all around us. We're exposed to it in many ways but the main sources tend to be tobacco, cured meats such as bacon, fermented foods such as beer and cheese, shampoo and cleansers and detergents and pesticides." Do you know what that --

A. I think you said "posed," and I think it's "exposed." So we're exposed.

Q. Oh.

A. I do know that there is exposure through sources in our diet and our environment, yes. I don't know if that's entirely accurate based upon any particular product. Certainly I think generally, it is found in other products.

Q. Do you know whether any of these products can be manufactured in a way that doesn't result in NDMA formation?

A. I've not done an assessment of that, so I can't answer that for you. I'd have to go, I'd have to look at individual products. It would be a product, not a category-by-category necessarily, but a product-by-product assessment.

Q. Is there any literature that says a risk assessment turns on whether the exposure can be controlled?

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MR. VAUGHN: Objection to form.

A. I don't understand your form.

Q. You testified you are aware that a risk assessment can turn on whether this exposure can be controlled; for example, you said sometimes you can't exclude NDMA from a product. And I'm wondering if there's anything in the literature that says that a risk assessment should -- should assess whether or not the exposure can be controlled.

MR. VAUGHN: Objection, form, misstates prior testimony.

A. I don't think I used the word "turn," but I may have used a similar word. But here's my answer for this:

In my experience and training and all of my work for regulatory agencies, in a variety of contexts, not just at FDA, risk assessments that are done for products often are affected by decisions that are made about whether there is exposure or not. So if exposure can be controlled, such as that it does not occur, then a product may be able to remain on the market.

So for example, if a product -- if the

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issue is a -- something within a product or some aspect of a product that potentially could pose a cancer risk by inhalation, but you're not inhaling this particular product or compound in this product, it's not going to happen, then you can control for the exposure even though it may have something in it that could pose a risk by inhalation.

So all risk assessments that I'm aware of, that I'm involved in, were for products that are regulated in the U.S., have an exposure component to them considering the likelihood for exposure, ways that you can be exposed, and that goes into the risk assessment.

It's kind of like the second step. First you do the hazard, then you do the exposure, Andy you do the dose response if you can, and then you do the -- you characterize the risk based on the exposure and hazard.

Q. Did you do all four of those steps here?

A. I did not do a dose/response assessment, which is what would be the specific cause issue to do. And I did not do individual causation exposure assessments for anybody in the case. But certainly I looked at what the regulatory bodies did and the companies did or didn't do in this area.

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Exposure, for example, is going to happen in terms of taking something orally. So we know that these are pills that are meant to be taken. So this is not like the issue of can they inhale. They are ingesting it, you know that's the case.

We know that nitrosamines from the general literature are indeed able to be absorbed once ingested. So those things I know just generally occur. So I didn't, you know, consider that as part of my training and experience.

But I did not do individual assessments for how people, individuals might take the drug, daily, weekly, those kinds of things.

Q. Did you do all of the steps in a risk assessment methodology in this matter?

MR. VAUGHN: Object to form.

A. I was not asked to do the full risk assessment for individuals, so I did not go to all the details of that. That was correct. I used the -- I used the methodology that I typically use when I'm developing regulatory opinions. And then in toxicology, I did a -- a hazard assessment and whether or not there was evidence to indicate whether or not this was a compound that would pose a risk only at a particular level. That's what we talked

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about already. I told you that because of it being a genotoxin and acting as a carcinogen. There is no threshold of no risk.

Q. Did you apply a weight-of-the-evidence methodology?

MR. VAUGHN: Objection to form.

A. Based on the doc --

THE WITNESS: I'm sorry, Brett --

MR. VAUGHN: You're fine.

A. Based on the documents I reviewed, yes, I did. I looked across the evidence in the case for certain opinions. Not every opinion would make sense to use weight-of-the-evidence.

Weight-of-the-evidence is typically used, for example, when I have my section where I talk about the toxicology and the potency of NDMA and NDEA, or nitrosamines, that's a weight-of-the-evidence form.

When I talk about the weight of the evidence in terms of what did I see that the company knew or didn't know, I -- there I am looking at information that is coming from all the available sources, so I'm weighing that together to tell a story or to see what story is told.

I also looked at, for example, defense

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expert reports that -- in this case, actually were available before my deposition. Sometimes those aren't. So I did look at the defense expert reports that dealt with my area, and just like I looked at some of the Plaintiffs' expert reports.

Q. What methodology did you apply to determine that there's an increased risk of cancer?

A. That would be my training and experience and the issues related to weighing the evidence and the issues based upon statements and information that's available. Is this something that's taught in textbooks, that you give a weight to that kind of evidence? Is it something that you only have one or two papers and then you have to determine whether or not those papers are reliable enough to make the determination? When authoritative bodies have reviewed this for the last fifty years, that's important weight in the evidence.

So in those opinions, yes, I did, I weighed the evidence and the sources and the -- in my experience, the reliability of those particular types of sources.

Q. Do you identify in your report all the evidence that you weighed in determining that there's an increased risk of cancer?

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A. In my reliance materials, it shows you all of the information that I have reviewed and weighed, yes. So you have to -- you can't just look at the report, you have to look at my appendix C as well, depending on the question you're asking.

Q. Does the report itself set forth how you conducted a weight-of-the-evidence analysis, what evidence you reviewed, and what conclusion you reached based on that evidence with respect to increased risk?

MR. VAUGHN: Object to form.

A. I believe that the totality of my report, which includes all my appendices, do, yes.

Q. In the actual language of the report, excluding your appendices, can you point to me to where you set forth which evidence you reviewed in determining, and which evidence you weighed in determining that there's an increased risk of cancer?

MR. VAUGHN: Object to form.

A. I think I tell you that. So -- hold on, let me look.

(A pause in the proceedings.)

A. Trying to find the right section. Hold on.

(A pause in the proceedings.)

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A. In section 6 in my report, if that's the one you're asking, that question, I think that's where this question would come, the answer to your question would come from.

So I set forth the textbooks, the authoritative bodies that I have reviewed and relied upon, and I think some -- I usually in here will make a comment about my training an experience, but I think I did that up front. Up front I tell you that when I -- the opinions here were developed based on not just the documents, but my training and experience as well.

Q. My question -- that's not my question. My question is, where can I see evidence that you weighed and how you weighed it in your report?

A. I'm telling you, the evidence that I have weighed and reviewed and relied upon are found cited in this section on toxicology of nitrosamines and then there may be additional materials that are listed in appendix C as well. In my depositions, typically -- typically that's the opportunity for you to ask me this question and I will tell you what it is that I have -- that I have reviewed and relied upon, in addition to how I describe it in my report.

And I'm telling you, it's my training,

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my experience, my prior knowledge of these compounds, what the authoritative bodies and the textbooks have said about it, what FDA has said about it, what the companies themselves in their own internal e-mails have said about the product.

The NTP document and the IARC document that I cite to are weight-of-the-evidence documents and so I have relied upon those, and I have reviewed, for example, I've reviewed the entire section of the IARC document that talks about all the different animal studies and human evidence and whatnot that dealt with nitrosamines, and specifically the NDMA and NDEA. So that accomplishes this section that I'm talking about.

Q. Dr. Plunkett, you're not really answering my question, which was very simple: Is there a place in your report where I can see how you weighed each piece of evidence? How you --

MR. VAUGHN: Object.

Q. -- your methodology --

MR. VAUGHN: Object to form, asked and answered. I objected to form, asked and answered. Move on.

MS. MILLER: Come on, Brett, let her answer it.

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Q. Is there a place in your report where I can see how you weighed the evidence --

MR. VAUGHN: Objection.

Q. -- which evidence you gave more weight to, which evidence you gave less weight to, the actual methodology; not your expertise, but see the methodology. Can you point to paragraphs in your report that do that?

A. So I -- what you're asking me doesn't make sense for a compound like this, where I do tell you the documents I relied upon and I cite to those specifically. And those are themselves weight-of-the-evidence reviews and dissertations.

I tell you in my methodology, it's there, that the way I do weight-of-the-evidence is consistent with the way bodies around the world may do it. I mean, I don't understand what you're asking me.

I didn't -- there was no need for me to perform another IARC review of all of the studies when IARC is a body that is relied upon by FDA, Health Canada, and toxicologists generally and I have reviewed that and made my -- my assessment that their review covers the breadth and the scope and uses the methodology that's consistent with how a toxicologist

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would look across the literature.

So I don't quite -- I mean, your question would make sense if you were asking me about a compound that no one else had made ever, but this is not the case here.

Q. So is it fair to say you're relying on other people's weight of the evidence and --

A. No. I performed my own weight-of-the-evidence assessment based upon the sources I have cited for you, and I'm just trying to explain to you the reason why I don't lay out each individual study is because that was done very thoroughly and very well in the documents that I cite to you.

So do I rely on the fact that they are complete assessments? I do rely on those documents but it's also something that I have done in the past. I'm very familiar with the IARC assessment of nitrosamines and MDNA. I have used it, reviewed it a number of times over the years, and it is a reliable document and a good assessment that goes through strengths, limitations, weaknesses, all of those things.

I have reviewed that. I agree with their assessment in terms of what I also know is

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consistent with every other regulatory body that I've ever seen that has assessed the carcinogenity -- carcinogenic potential of NDMA and NDEA. FDA talks about that specifically as well. And I have relied on that when looking at FDA's conclusions about what they say about these compounds.

Q. Did you review animal studies related to NDMA?

A. As they were cited in the NTP document, yes, because very specific and detailed data table there, so I did.

Q. Did you go back to the original studies or did you just rely on what NTP said about them?

A. I answered that for you. I said IARC first off, but also NTP, they both do it. I have seen the reviews of -- by both of those -- those bodies, and I've seen the references, I've looked at the summary of the information, but I did not redo their analysis. There is no need to. Again, there's no controversy in my view. I challenge you to tell me there's a controversy that NDMA does not increase the risk of cancer, because it does.

Q. Do you know whether the dose of NDMA addressed in the animal studies is similar to the dose that has been found in Valsartan?

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MR. VAUGHN: Object to form.

A. So that's a different question. So as all animal studies are done, they have to do an exaggeration of dose because animals don't have the same susceptibilities or sensitivities that humans do. It's a general principle of toxicology, when you design a cancer bioassay in animals, that you will use dose ranges that start out, you always have a zero and then you have a level that may or may not be similar to what humans may be exposed, but you exaggerate it because the idea is, you want to be able to show that you have tested the system of the animal to such an extent that you can rule out, if possible, that the product is or is not a carcinogen. So you can make that determination.

So you need to see your -- you're hoping to see some type of pathology that would indicate yes or no, there's a carcinogenic result.

You also start in cancer risk assessment bioassay development and dose collection with results from the genotoxicity evaluations that are done, and you use those to also help set your doses, but they are not the same. The human exposure doses could be very different, depending upon the situation you talk about.

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Q. So you're saying that the animal studies had doses of NDMA that were higher than the doses that Valsartan users are exposed to?

A. I can't tell you that that's the case for every Valsartan user because I don't know what every Valsartan user took. But I can tell you that the doses that were used in the animal studies were chosen based on sound scientific principles and clearly show every study, regardless of the dosage use and the route of exposure, even a single dose in a prenatal study showed that NDMA was carcinogenic and by definition, it's something that's carcinogenic and if you're exposed to it as a human, you're increasing your risk of cancer.

Q. If something is carcinogenic and you're exposed to it as a human, you're increasing your risk of cancer regardless of dosage?

A. You're -- increasing the risk is not the same as identifying a dose. Increasing the risk of cancer is a statement about hazard. It is telling you that when you're exposed to this, the properties of this chemical have the ability to be carcinogenic. And so you increase your risk. There is no safe dose of NDMA that's been defined. There's -- there is instead a -- you can make a determination whether

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it's acceptable to increase cancer risk more than one in a million or not. That's the decision. And those decisions for regulators are in a different context. But as a scientist, that's what you do, you calculate the slope of the dose/response curve and you extrapolate to zero because there is no "threshold" for cancer.

Q. So is it your opinion that any exposure to NDMA increases the risk of cancer?

A. I have not -- I haven't formed an opinion of any specific dose but exposure to NDMA generally, that's exactly right, increases your risk of cancer.

Now, you say "any exposure," you need to explain to me what you mean by that because, could I come up with an exposure that may be -- it's possible. But in terms of these products in this case where you're orally ingesting these products, that is my opinion, purely and simply, that the exposure to Valsartan products containing these impurities increased -- increases the risk of cancer in people who take the drug. And then, there you have to go and talk about individuals and that's not what I have done. There's an indication to do that.

Q. Would any exposure to NDMA through

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Valsartan increase the risk of cancer?
MR. VAUGHN: Objection, vague as to "exposure."
A. I answered that. I said I believe that in this case, based upon what I know is occurring, that your risk is increased with your exposure to the impurities in Valsartan. It increases your risk because of the issue that there is no threshold or safe dose that's been identified for a cancer-causing ingredient.
But there's another concept, which is what the regulator applies, and that is making a, in this case, making a risk/benefit decision based on -- actually it's a risk/risk decision, not a risk/benefit -- they are looking at whether or not the exposure -- the FDA is -- whether or not the exposure to impurities in Valsartan is riskier than someone who doesn't take the drug, and those are things that regulators do.
That is not what I'm doing. I'm telling you as a scientist that this particular drug with these impurities present, if those impurities are present, you're increasing the risk of cancer in individuals who take the drug.
Q. If we could go to the third paragraph on

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this document, on the screen, Exhibit 5, first sentence says, "According to Health Canada, the average" --
A. Hold on a second, I need to find it -- okay, I see it NOW. Okay.
MR. VAUGHN: Are you on page 3?
MS. MILLER: Yep.
Q. "According to Health Canada, the average levels of NDMA found in these pharmaceuticals are not expected to pose a significant increase in cancer risk."
Do you disagree with that statement?
A. I don't -- I haven't done that assessment so I can't agree or disagree with that, because I haven't looked at a specific population of numbers of levels to make that assessment. That's a different assessment.
But I point you to the fact, you'll notice they don't say there's no risk, and that's the point I'm making to you, that no one is saying there's no risk.
Q. Do you have an opinion as to whether the average levels of NDMA found in these pharmaceuticals is expected to pose a significant increase in cancer risk?

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MR. VAUGHN: Objection, form, vague as to "these pharmaceuticals."
A. I don't believe I've formed opinion on a specific level at this point in time in Valsartan, if that's what you're asking me. So if you're talking about Valsartan, at the levels that may have been detected in any one pill, at any one particular point in time, that was beyond the scope of what I did, but -- but, I would point you to the fact that the regulatory agencies are not saying there was no risk.
They are making a judgement based upon a situation they are in which is balancing drug shortages, they are balancing people stopping to take the drug, there's a lot of things they are balancing, and why they all concluded that this stuff shouldn't be there and it needs to come out.
Q. Let's look at the next sentence from there. "A person taking a drug that contains NDMA at or below the acceptable intake every day for 70 years is not expected to have increased risk of cancer."
Do you see that?
A. I see that.
Q. Do you agree with that statement?
A. I don't agree with that statement as specified because there's more to it, if you actually

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look at what FDA and Health Canada say. They actually put it in the context of the number of cancers that you would expect to see over a lifetime and it wasn't zero.
So again, I would -- I would disagree that you would not expect -- you have an increased risk. The question is, how -- what is that increase, and how do you weigh that as a regulatory agency in terms of making decisions on drug availability.
Regardless of that, however, again, both of these regulatory agencies are on the record saying that the NDMA should not be there, and they want it gone.
Q. According to this article, a representative from Health Canada stated that a person taking a drug that contains NDMA at or below the acceptable intake every day for 70 years is not expected to have an increased risk of cancer.
Do you agree with the Health Canada statement there or not?
MR. VAUGHN: Objection, foundation.
A. I don't know what else was in the e-mail so I haven't formed an opinion. I wouldn't form an opinion I agree or disagree with this statement taken by itself. But I would tell you I have seen other

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descriptions from the regulatory agencies where they are -- they are not saying that there is no increase in risk, which would be the -- which would be what you would be taking from this if that was -- if that was the case.

Q. Have you seen a statement from Health Canada saying that it believes there is an increased risk?

A. I'd have to go back and look at the Health Canada website again. But what I have read from Health Canada is consistent with them also understanding that there's an increased risk of cancer with exposure to NDMA, and that it is something that they do not want in the drug supply.

Q. Is it your testimony sitting here today that Health Canada has stated that taking Valsartan that had NDMA or NDEA impurities would increase a patient's risk of cancer?

A. If you're going to ask me that specific question, I'll have to go back to the Health Canada website to look. I'm just telling you my interpretation or my take-away from looking at the positions of both bodies is that this is something that isn't supposed to be there. The companies can make -- ZHP can make the product without this

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contaminant, or this impurity, I'm sorry, different regulatory term, contaminant. They can make it without it, and if they can make it without it, that's what the agencies want to happen.

Q. I understand that, but has Health Canada stated that somebody who took Valsartan with NDMA impurities as was at an increased risk of cancer?

MR. VAUGHN: Objection, asked and answered.

A. That same answer. To find a specific statement I'd have to go look, but that would not be consistent with the overall methods or the overall conclusions I have seen the agencies make.

Q. Sitting here today, do you recall any statements by Health Canada that taking Valsartan with NMDA or NDEA impurities would increase a person's risk of cancer?

MR. VAUGHN: Objection, asked and answered.

A. Same question -- same answer. I would go back and look at the website and scour it again. But when I looked at the website, I wasn't looking for a particular sentence. So I can't answer that at this point in time without looking.

But again, I would point to the fact

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that in both cases, the agency is aware that there is a way to make the drug without the contaminant, or without the impurity, and that's what's important. If you can make it without it, then there is no risk because it's not there.

Q. Do you believe that a person who took Valsartan for 70 years that contained NDMA would have had an increased risk of cancer?

MR. VAUGHN: Objection to form.

A. I answered that for you already. I told you I have not done a calculation in that way, so I can't answer that. That's somewhat, other people are doing that, and I would refer you to the other experts who are doing these kinds of risk assessment coverage.

Q. So you do not have an opinion as to whether somebody who took Valsartan for 70 years that contained NDMA would be expected to have an increased risk of cancer?

A. I have not formed that exact opinion, but I have formed the opinion that the presence of NDMA and NDEA and other nitrosamines like those that are potent genotoxins in Valsartan drug products increases the consumer or the patient's risk of cancer. That's my opinion, and I think that's

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consistent were what I've said in my report.

Q. So you have an opinion that it increases the risk of cancer generally, but you don't have an opinion whether it increases the risk of cancer if you take it for 70 years?

A. Because I have not done that calculation. When you're asking me that question, that was beyond the scope of what I did. So again, I don't know what else to tell you, but I know there are other experts in the litigation who are doing these calculations, and I'm sure they'd be happy to answer the question, because they've all done those calculations.

Q. Are you offering an opinion in this litigation as to whether Health Canada was correct or incorrect in making this statement that we just read?

MR. VAUGHN: Object to form, foundation.

A. I have not formed an opinion like you're describing at this point in time. And typically I would not because all of this that you're talking about, the issue is the duty -- what is the duty of the company; and it's the company's responsibility to make sure that their products are safe for use, regardless of what Health Canada says or FDA says.

Q. We're not talking about obligations and

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duties right now. I'm asking you whether or not you agree with Health Canada that a person taking a drug that contains NDMA at or below the acceptable intake every day for 70 years is not expected to have an increased risk of cancer.

MR. VAUGHN: Object to form, foundation. There's no evidence that Health Canada made the statement.

A. I've answered this question I think for you five times already, and I'm not changing my answer. You know, again, I have not done a quantitative risk assessment. I have not -- which is what you would be doing here. I have done an assessment based on the hazard that is posed, which is an appropriate standard in terms of the regulatory world when you're looking at the statements these agencies make about -- about this situation, that it's unacceptable for this to be there.

And then they acknowledge that you can make the compound without it. Diovan with the TIN process apparently was made without it. So again, I -- I'm not trying to evade your question, I'm just telling you that's all important context here. When you ask these questions, do I agree or disagree with the regulatory agency, it's not as simple as that,

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and I have not formed an opinion that I agree or disagree with any particular one sentence from regulatory agency.

Q. Are you offering an opinion as to whether Diovan contained NDMA or NDEA?

A. I have an opinion related to that later in my report, where I talk about the evidence that I have seen indicates that it is not present in Diovan, and I have not seen evidence to indicate that the -- the opposite. Do you need me to tell you where I say this or --

Q. No, I don't. If Diovan, if some of the Diovan manufactured by Novartis had trace amounts of NDMA or NDEA, would that change your opinion that ZHP's Valsartan is adulterated?

MR. VAUGHN: Objection.

A. I don't think it would change my opinion that I would deem them adulterated because the presence of those particular compounds, as the FDA concluded, was that they were adulterated. And the fact that they were being produced outside of good GMP on top of the presence of those impurities would, by the definitions, the regulatory definitions, deem them adulterated. That's in my report as well.

Q. Did you undertake any investigation as

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to whether any Diovan ever had trace amounts of NDMA or NDEA?

A. I looked for information in the files or the documents that I had access to, and I also looked, I saw a document, the one I cite to, I think I tell you, let me look for it...

(A pause in the proceedings.)

A. The analyses, I've seen an analysis by Health Canada of Diovan samples and I cite you to the source for that. The Diovan was listed there as it not being defective. And again, if you look at all of the things that are said, other evidence in this case where these different changes in the process are discussed, the company themselves recognizes that there's a difference between the TIN process that is used for Diovan versus their process in terms of the potential for the formation of nitrosamines.

Q. Is it your opinion that because Health Canada did not find nitrosamines in the Diovan it tested, that means that no Diovan ever had nitrosamine impurities?

A. No, my opinion is that the testing of Diovan demonstrates that this particular drug had been manufactured without nitrosamine impurities. That's my paragraph 61.

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MR. VAUGHN: Hey, Jessica -- sorry, Dr. Plunkett.

A. I'm citing to the Health Canada. I have seen no document that indicates that Diovan had the same problem as the API that was made by ZHP, sold under ANDAs by ZHP companies for Teva or Torrent.

MR. VAUGHN: Jessica, I know you're on a schedule. What time do you want to do lunch?

MS. MILLER: 1 o'clock, four minutes.

Q. Dr. Plunkett, in preparing your report, did you speak to anyone who worked at ZHP?

A. No, I've read deposition testimony but did not speak.

Q. Did you speak to anybody at the FDA?

A. No, I've not -- well, I've not spoken to anyone at the FDA. I think what you mean is, having to do with this particular project, no, I have not.

Q. In preparing your report, did you speak to anybody who consulted with ZHP?

A. I don't believe, no. Some of the people that I know wrote reports. I've not spoken to any of them.

Q. And you did not speak to any organic chemists in preparing your report either, did you?

A. No.

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Q. Who put together the documents that you reviewed in this litigation?
A. Oh, I do, as I typically do, I ask for documents. Once we had a discussion of what areas the attorneys were looking for me to address, which is general toxicology and general regulatory responsibilities, I then asked for certain kinds of documents.
I also asked them to send me certain kinds of deposition testimony that might be related to my opinions and then I asked for the expert report of the chemist in the case. That was provided. Plaintiff's expert. And then, as I always say to them, "Certainly, please send me, if you get them, defense experts that cover the same area I do." That didn't come, however, until after my report was drafted. Those were made available to my around the 23rd of December or 21st of December or something like that.
Q. Do you have confidence that you reviewed all the documents that are relevant to your opinion?
MR. VAUGHN: Object to form.
A. I have confidence that I have reviewed sufficient evidence to form and reach the con -- all my opinions and reach the conclusions I have drawn.

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Q. Do you read Chinese?
A. No, I do not.
Q. Were all the documents in this litigation written in English?
A. No. But the documents that I have reviewed and relied upon that were not in English had English translations that were provided to me that, as is typical in litigation. This isn't the first litigation I've worked in that has had translated documents.
Q. Do you know whether all the documents that were important to you forming your opinion have been translated into English?
MR. VAUGHN: Object to form.
A. Any document that I've ever reviewed and relied upon I had an English translation for. So that's the only way I can that question. And I would also indicate, I actually, when -- one thing I did do, this is not in my report obviously because it was after, one of the things I did do was, I looked at what may or may not have been described within reports of other experts in the case to -- but I didn't see anything that would have changed my opinion.
Q. Have you prepared supplemental reliance

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listings to include all the documents reviewed after submitting your report?
A. The attorney -- Mr. Vaughn, I asked him to provide that as part of your notice of deposition. He did do that.
Q. Did you go into any databases on your own to search to documents that might be relevant to your opinions?
A. Are you asking for confidential documents or for publicly-available documents? Publicly available, certainly I did. I did my own literature searches and I looked at the FDA website. I looked at the FDA website for any type of information that I could -- I could get to that was related to my opinion.
(Continued on following page.)

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You're asking about confidential documents, I asked those to be provided to me in certain areas, but I did not search the database on my own, no. It's apparently very, very large, from what I understand.
MR. VAUGHN: Ready for a break, Jessica?
MS. MILLER: Sure.
MR. VAUGHN: Great.
VIDEOGRAPHER: Going off the record. The time is 1:00 p.m. This is the end of media unit 2.
(Luncheon recess: 1:00 p.m.)

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A F T E R N O O N S E S S I O N
(1:43 p.m.)
L A U R A P L U N K E T T , having been previously sworn, resumed the stand and testified further as follows:
VIDEOGRAPHER: We're back on the record. The time is 1:43 p.m. Eastern Time. This is the beginning of media unit 3.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. Dr. Plunkett, does a generic drug have to have the same exact impurity profile as the reference listed drug?
A. It has to have the same impurity profile per the monograph, which would be the Reference Listed Drug, yes. You would expect it to have the same impurity profile as listed in the compendium.
Q. When you say the monograph, do you mean the USP?
A. Yes, exactly.
Q. And did the USP monograph for Valsartan require the identification of impurities over .1 percent?
A. At the time that the ANDAs were approved in this case, no, but there's a separate issue in

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which it has to do with, you would need to identify things that were below .1 percent, based on your chemical process assessment, if they were potent toxicants or genotoxic.
Q. So where does it say that?
A. That is in the guidance information that I cite in my report where I talk about the -- want me to try to find it for you? Or, it's in my report, I know I discussed this.
Q. You said it's in the guidance document, right?
A. Yes, that's correct.
Q. What's a guidance document?
A. Guidance document is a document with a -- depending on who it is. So let's say, either USP or FDA, because FDA adopts USP standards and guidance in many cases. It's a document that sets forth the current thinking of the regulatory authority on what standards or rules should be applied in a particular situation, and also sets forth and tries to answer often questions that have been raised in their experience to give examples and nor specific information, because the regulations are often broad, not specific, right? The regulation is broad to, for example, GMP for all human prescription

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drugs, but there may be in the guidance documents a need to understand that some drugs may have different issues addressed and the guidance will help you with that.
Q. Do FDA guidance documents establish legally enforceable responsibilities?
A. I'm not a lawyer, but based upon the discussion in the documents themselves, there's always a disclaimer statement, I guess, on the front of most FDA guidance documents where they talk about things not being legally binding; however, when you read the documents, they also talk about some of the guidance statements having directions such as "shall" versus "can," and so there are some statements in the guidance documents that are expectations in terms of what would be complied with.
So in my experience, guidance documents, since regulations are a minimum set of standards, guidance set out some additional standards that the FDA expects to be used when developing quality systems our compliance programs within companies.
Q. Has the FDA stated that guidance documents shall only be viewed as recommendations?
A. That's what I just told you. There's a disclaimer in the front that, if you read further

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into almost every guidance document in the introduction section, it also talks about, besides that disclaimer, it also talks about the language that may be chosen to be used in the guidance document.
I'll also point out, based on my experience and training, that one of the reasons that guidance documents may not become final rules or actually be set into regulations is because of the recognition of how long it takes to get those things there. So many times, guidance documents are issued because it's FDA's quickest and fastest way to get their thinking out to industry on what they would like to see.
Q. Has the FDA stated that the use of the word "should" in agency guidance means that something is suggested, recommended, not that it is required?
A. That could be the -- I don't know if it's exact language, but there's something similar to that, yes, in there, yes. And -- well, not in -- I don't know about every guidance document, but in many of the ones that are issued here, yes, that's correct.
Q. So do you agree that when the FDA uses the term "should," that's not establishing a duty,

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it's just establishing a recommendation?
A. It's different. So I would agree with you that it's establishing a recommendation, but duty is different. So manufacturers have a duty to insure at all times during the life cycle of their product that it's safe and effective for the use as indicated. As a result, the manufacturers have a duty to do what they need to do to make sure that's the case.
So I wouldn't use "duty" in that language. I would say, I would agree with you that they -- that you made a comment about it being a recommendation, but earlier on you told me you were not talking about responsibilities or duties.
Well, the guidance documents set forth a little more than the minimum, but there is a separate duty that each manufacturer has, things they need to do and it's industry practice in my view, and the companies I've worked with, is, they typically do what is in the guidance documents when specific guidance is given on an issue.
Q. Just to make sure I understand, because I'm not sure I understand your testimony, is it your testimony that the FDA guidance imposes duties on manufacturers?

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A. The guidance impose -- no, I said the guidance imposes a -- it's FDA's thinking or their recommendations. Now, if they use the word "shall" in a document, that's different. That's something they are saying will be done, right? But when they use the word "should," you're exactly right, it's part of the recommendations.
But then I said to you, based on my training and experience, working with industry and complying with guidance documents, industry, responsible manufacturers will take that information and use it as their standards that they will apply -- more specific standards they will apply as part of compliance with the general regulation in that area, if it relates to them. I mean, there may be a guidance issue that doesn't relate to that particular company and if it does, it's my experience that they would use that guidance and attempt to comply with it, if they can.
Q. Are you using the term "duty" differently from "legally enforceable responsibility"?
A. I'm using "duty" -- I'm not a lawyer so I'm using "duty" -- their duty as a responsible manufacturer based on my training and experience, so

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that's how I'm using that word. So they have a duty.
Now, the law, you're right, the law has some very specific duties that are laid out, and one of those is the one I started with, which is, it's the duty of the manufacturer to ensure that the product is, remains safe and effective throughout its life cycle for its intended use. It's not FDA's responsibility or duty, it's theirs.
So the company, those regulations and the standards and all of the things that we're talking about are things that the company needs to be doing, because it's not -- FDA isn't the one that is manufacturing the drug. FDA is not the one that's selling the drug. FDA is not the one that's making the profits off the drug. It's the company. So they have a set of duties because of that role that they play.
Q. Where is that duty codified?
A. That's looking at every responsibility set forth in the FDA regulations. If you go back to Section 200 throughout, 300, 400, sections, it's 21 CFR, and look at what is the responsibility of a manufacturer. A manufacturer is the one that has to do this. The manufacturer is the one that has to do that. And then if you go to some of the general

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statements at FDA's website, and if you need to explore a specific site I'll have is to go find it, but there's general statements on what is the responsibility of a drug manufacturer, and they talk about those specific things that they must do. It's their responsibility to do testing, it's their responsibility to put together the application. It's their responsibility to have post-market surveillance in place, it's their responsible to have a quality management system in place. All of those things are in the regulations linked with the manufacturer, not with the FDA.
Q. Have you read the MSP complaint?
A. I don't know what you're referring to.
Q. Have you read the complaint in this case?
A. If it was on my reliance materials, I may have looked at it, I'm not sure. Can you tell me -- let me look, I have my appendix C. Hold on. If I have, it's been a while, I don't know.
Q. Do you remember reading the complaint in this case?
A. I have no specific memory. I often do, though, that's why I'm saying that. So let me look and see if you want -- if you want a specific answer,

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if it's in my reliance list, I have.
Q. Okay. So your reliance list, maybe this will be helpful, your reliance list is appendix C, and it's one, two, three, four, it's four-and-a-half pages, double columns.
Did you read every single document that's listed there?
A. Yes, I have looked at every single document that's in here, yes, at some point in time. That's why it's listed. Many of -- let me just say, many of these documents are -- were Bates-numbered exhibits to deposition testimony as well.
Q. And what's the difference between "looked" and "read"? I just want to make sure I understand. I asked, did you read, and you said, "I have looked."
A. I have -- look, every document here has been opened up, I may have read it, I may have skimmed and read some more thoroughly, it depends. For example, on some of the deposition testimony, I may not have read every word but I certainly skimmed through the entire deposition and I compared the exhibits, to look at the exhibits, to see if they are relevant to my area of expertise because there were some depositions that some of the information that

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was being discussed was beyond the scope of the opinions I was forming. But I would -- all of these documents would be fair game if you want to go and look at one, and I can tell you my opinion, how it does or doesn't support my opinion, or what it was -- what it is or is not relevant to.
Q. Are you offering an opinion in this case as to the conditions that are necessary for DMF to degrade?
A. No. I believe that's what the chemist is doing. I cite to the fact that -- I think I talk about what the different processes were, and I point out some of the observations about what the agency, FDA even identified was there, or the company was aware of was there, based on deposition testimony. But I have not done an independent analysis. That would be what the chemist has done in terms of foreseeability.
Q. Does ZHP have Quality Management Systems in place, QMS?
A. Well, they supposedly did, based upon the documents I've seen, but this is one of the things that they got cited for in terms of their FDA warning letter on the inadequacies of some of their Quality Management System issues. So you could have

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a Quality Management System that isn't adequate, and you can have a Quality Management System that is robust.
Q. Are you offering an opinion that the Quality Management System was not adequate?
A. That was beyond the scope. Dr. Bain, I believe, is addressing those specific issues in terms of the case. Maybe also someone else, but I've read Dr. Bain's report and I know she addresses that to some extent.
Q. Did you speak to Dr. Bain?
A. No, I haven't spoken to any of the -- to short-circuit it, I haven't spoken to any of the experts on either side much this case.
Q. Were you familiar with Dr. Bain before you got involved in this litigation?
A. No I was not familiar with her.
Q. Were you familiar with Dr. Hecht before you got involved in this litigation?
A. No, I was not.
Q. You mentioned the warning letters, correct?
A. Yes, I have.
Q. What's a warning letter?
A. A warning letter is a administrative

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action that can be taken. It's a tool that the FDA uses once they have had an inspection, typically for example, of a facility. And if the inspection has identified regulatory compliance issues that are significant, the FDA will send a warning letter. Sometimes the warning letter doesn't come immediately, sometimes they have a -- a untitled letter or a discussion that they have with the company to try to achieve compliance or solve compliance concerns. And if -- but if those things don't happen, then another warning letter can follow as well around the things that weren't resolved.
But it is an action that must be responded to, so I think it's 15 days, basically 15 days after receiving a warning letter to respond to the agency with something, saying that, you know, what they are planning on doing or -- they -- I've helped companies in the past respond to warning letters.
For example, sometimes the response is, "We have engaged with a consultant who is going to be coming to our facility on XYZ," or, "We've engaged an attorney that will be assisting us with changing or revisiting some of these issues and then we'll get back to you," and then the FDA expects a follow-up.

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Q. Has the FDA stated that warning letters are informal and advisory?
A. Yes. They -- well, I know they are informal, but to me an entitled letter is what I would call informal. It's possible that FDA said that, but when I talk with my clients, I talk about a warning letter as being something that's serious and has to be addressed, because there's a time issue with it.
But there's advisories. They are telling the company what problems exist that need to be addressed, so in that case, yes. And in that case, it's not an enforcement action such as a recall or a banning or a criminal, you know initiation of criminal procedures, a lot of different things that could happen. It's not an import alert, which is a more formal action that should be taken.
Q. Are you familiar with the FDA regulation or procedures manual?
A. Yes generally, yes. Some sections more familiar than others.
Q. Do you know whether that manual refers to warning letters as informal and advisory?
A. I'd have to go back and look. I don't recall any of the specific language in it.

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Q. Is a warning letter considered final agency action?
A. No. Again, it requires a response. So that could lead to formal -- typically in my experience, a warning letter gets responded to and then the agency, the FDA will respond to your response with a closure of an action or, you know, indicate that additional -- additional work may be needed.
Q. The FDA expressly has stated that warning letters are not final and binding, right?
A. Well, obviously they are not final because follow-up is expected. I don't know what you mean by "binding." If what -- by binding, what they are meaning is that you can make an alternative argument and they will consider it, that is true. In other words, what the findings are in a warning letter may change or the opinion of the agency could change depending on the information and arguments presented by the affected party, if that's what they're saying.
Q. Fair to say --
A. Again, if you're referring to the regulatory procedure manual, then I'd have to look, I don't know, that is fair.

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Q. Is it fair to say that a warning letter is issued to achieve voluntary compliance?
A. Yes, that's the -- FDA is always using a carrot rather than a stick first, unless there is something very, very serious that has risen to a level of criminal, in which case the stick may come right out.
Q. And if you undertake corrective action, the FDA can close out a warning letter, right?
A. Yes, that's what it said, that's typical of the actions that can happen, so that would mean a finalization of the process for that particular issue raised in that warning letter.
Q. Do you know if the FDA closes out a warning letter, what does it mean?
A. It means that for the issues raised in that warning letter, there has been some action or information provided to -- that makes that warning letter issue either moot or has been resolved. So for example, you could make the issue in the warning letter moot if you said, "I'm just going to stop making the drug." You may, however, say, "We're going to put these processes in place, we're going to be putting in testing," to ensure, for example, like in this case, companies are expected to show that

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will there is no NDMA or NDEA or nitrosamines present before they release product, those kind of things.
Q. Are you offering an opinion that ZHP's QMS was inadequate?
A. You already asked me that, and I said that was beyond the scope. That's something that Dr. Bain, I believe, is addressing.
Q. So if that's the case, if it's beyond the scope, why do you mention QMS in your report?
A. To give context to why, what companies are required to do, because I talk about responsibilities, overall responsibilities of what a drug manufacturer is supposed to do, and I also talk about limitations of the FDA. And those are both important context opinions or -- not opinions, context to give when I talk about different issues in the case.
And I was asked in this case to provide a general overview of some of the important regulatory issues that the company would need to address, things they have to have in place, or things they should be doing in order to be manufacturing the drugs in compliance with, generally with FDA regulation.
Q. Other than the fact that you have

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testified already today that ZHP did not conduct, in your opinion, an adequate risk assessment, do you have any other opinions as to things that you believe ZHP did that were contrary to FDA regulation?

A. Well, several times in my report I say that they put patient health at risk because of the actions they took. They are not doing -- not doing the risk assessment, for example, to understand that they were selling a product, or marketing a product that had these toxic contaminants -- toxic impurities, carcinogens in them. I'll look, I mean, I have a couple of -- I have a summary -- I have a summary opinion --

Q. No, no.

A. -- at page --

Q. I don't think you're understanding my question. Other than the risk assessment requirement, are there any specific FDA regulations that you are saying ZHP did not comply with?

A. I don't think I state my opinion the way you're stating it. But I certainly do think some of my opinions are relevant to the question you're asking. I don't know how else to answer it. So you'll notice in my report, I think you'll notice in my report that you don't see a number of statements

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that say, "They violated this regulation," or, "They violated that regulation." Because that analysis was being done by, in my -- the information was given in the reports I've seen by other experts.

Instead, what I have provided, I believe, in my report, is, I have talked about what are the responsibilities of a manufacturer under the regulations, what regulations apply to them, and what issues I see.

And I see issues with the improper risk assessment, for example, which leads to them producing a product that I believe would be deemed adulterated. So I guess what I'm saying, it's being deemed adulterated, that's a violation of the -- of the regulations that deal with adulteration of products under the -- under both the law itself, section 351 CFR; and also other parts of the -- the quality regulations that talks about the need to produce a product that is -- that is not adulterated.

Q. Are there any other regulations sitting here today that you believe ZHP violated?

A. I believe they sold -- they sold a product that I believe was not pharmaceutically equivalent. So part of the regulations -- I mean, I give you sections -- I pull out certain sections and

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quotations, and some of those are out of regulations, some of those are out of the statute itself, so I know I address that as well, the issue of the fact that the drugs, the Valsartan products that contain NDEA and NDMA would be deemed adulterated; and as a result of that, they would not be pharmaceutically equivalent, and by the definition of "bioequivalent drugs," which have to be therapeutically equivalent and pharmaceutically equivalent, that would be an issue that I'm raising in terms of the regulations.

But it's -- I don't know how else to answer for you. I'd say that I was very -- I was very -- "careful" is not the right word, but I tried to be very specific and direct in my language I use so you understand what I am saying, and if I -- I typically, since Dr. Bain is the one, and others, that are doing GMP compliance, many of the regulatory issues that you would point to from these standards or parts of the 21 CFR that they are handling, and I did not do that.

Q. Is there a place in FDA regulations where it says bioequivalence means that you have the exact same impurity profile?

A. Well, let me -- there is a statement about purity. So hold on.

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(A pause in the proceedings.)

A. So paragraph 21, under the definitions of what is a pharmaceutical equivalent, and that comes from FDA's own regulations, "Pharmaceutical Equivalence," and goes on, goes up halfway down, and it says, "And meet the identical compendial or other applicable standard of identity, strength, quality and purity," and the purity is the issue, as it states here.

They were making Valsartan in ZHP, and I don't have any evidence to indicate their Valsartan tablets weren't of the claimed strength, but I have evidence to indicate that the Valsartan tablets had a different purity profile than the Reference Listed Drug, in the presence of the NDMA and the NDEA, and the lack of investigation they did to understand the chemical process.

Q. Does this sentence say that the two drugs have to have the same purity or does it say that the drawing must meet the identical compendial on other applicable standard of identity?

MR. VAUGHN: What page were you on of her report? I'm sorry.

MS. MILLER: We're on paragraph 21.

THE WITNESS: She had read the language

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to me.
MR. VAUGHN: I got lost.
A. Go back to the original question, though, because I thought what I was answering for you was what you were asking. So what is your question now? Say your question again, because maybe I misheard your question. I thought I was pointing to this because I thought this answered your question directly.
Q. Does a generic drug have to have the exact same impurity profile as the RLD?
MR. VAUGHN: Objection, vague.
A. So that was why I went here. So in order to be a generic -- in order for a generic drug to be legally marketed, it has to be bioequivalent. And "bioequivalent" includes two parts. It's the therapeutic equivalence; but it's also, as set forth here, the pharmaceutical equivalent. And I'm saying to you that if they are comparing themselves, which they are, they -- when I say "they," ZHP is making a product where their RLD is supposedly Diovan, and they use the monograph as a standard for that, and then they change the process, that they don't believe that that process is making any "significant changes" such that they would expect something different, but

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yet they don't investigate it. The fact that they then signed that they are making NDEA and NDMA, makes the purity of their drug different from the Reference Listed Drug, and I don't know how, more specific way to say it. I have it there, and I have other -- paragraph 22 I talk about it as well.
Q. You're not answering my question. My question is, what was the compendial and/or other applicable standard of identity?
A. You have to go to the USP monograph for Diovan for the Record Listed Drug, and we've already discussed this --
MR. VAUGHN: Let her finish her answer.
A. -- and we already discussed this, because you're asking specific questions about the compendial standard, and I think you mentioned .1 percent, .1 percent are the compendial standards, don't mention NDMA and NDEA. However, it doesn't mean that you ignore what you're supposed to do in order to make sure that what you're doing is making a product that doesn't have something that is not listed.
So for example, if the monograph had been approved such that NDMA was going to be allowed as a potent toxicant or genotoxicant, I would expect

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there to be a listing for that in the monograph and it's not there. Instead, what happens is, that drug in the monograph, made by the TIN process, was not anticipated or expected to make NDMA or NDEA.
When they changed the process, this is when ZHP becomes responsible for making sure that their changes to the process don't change the profile as they compare it back to the standard, and I'm saying to you, that's the problem here. They didn't -- because of not doing their, as they admit in their deposition testimony that they didn't do, and there are stipulations that they made that they didn't do a complete review of their process, and yet there's also discussion among -- of the fact that ZHP employees were aware that, in 2017, at least, that their process could produce genotoxins like NDMA. So that's what I'm pointing to. That's the evidence I'm pointing to, the paragraphs that describe it.
There's additional description of that issue I was bringing up about what the company knew in other parts of my report, and I can find it for you if you need me to.
Q. Where can I find everything you just said in the USP monograph?
A. Everything I just said is -- I don't

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understand. Some of what I just said to you is my opinion based on the evidence that exists. Are you asking me -- what are you asking me? What, everything that I just said? Because I did say a lot, I apologize.
Q. The USP monograph simply says not more than 0.1 percent of any other individual impurity, correct?
A. Yes, but there's also -- there is also the understanding with these monographs, when you go to the USP website and also to the ICH guidance that goes along with all of these issues, that that statement for .1 percent does not apply to potent toxicants or genotoxins.
Q. Can you show me where it says that?
A. In my report --
Q. No, not in your report. Where it says that in USP. Where does it say in USP that the term "any other individual impurity" does not actually mean "any other individual impurity"?
A. I don't understand your question. I'm telling you --
Q. It says here, "Any other individual impurity," that's the language in USP, and you're saying that's not what it actually means. Where can

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I go to USP to see that actually the term "any other individual impurity" has a caveat, the caveat you just referenced?

A. It would be the information that goes along with the implementation of the monograph. So it would be going back to the general -- there's general procedures, or general chapters USP cites that talk about impurities. So you go there, and you look at what they describe as far as impurities, and then you go to the ICH documents that talk about the monographs and the development of impurities. So that you can't look at just the USP monograph, you shouldn't be looking at the USP monograph in isolation from the other information that talks about how to use that monograph, is what I'm telling you.

The company in this case, "company" being ZHP, and then also Teva and Torrent, because they accepted what ZHP supposedly did, the issue is that they were making a product where they didn't have control of their process, and by not having control in terms of knowing what their process was doing, they were making something that had a genotoxin in it, and as a result that .1 percent any other impurity, based upon the complete evidence of how these monographs are developed and used, is

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inconsistent, and that's what I'm telling you --

Q. You keep answering questions I'm not asking. My question is very simple. Where in USP, where, what book in USP can I go to, to find a statement that "any other individual impurity" does not apply in this circumstance?

A. I thought I just tried to tell you that. I said to go through the general chapters on impurities where they discuss impurities. And then I also told you to go to the guidance documents put up by ICH which talk about implementation of some of these things.

Q. And that's --

A. I don't know what else to tell you. I mean, I'm trying to answer your question consistent with my experience but also, I mean, in my report, I lay this out. Maybe let's go to my report, tell me what it is that you don't agree with and I'll try to explain it to you. Obviously you disagree with something I've said in my report.

Q. Is it your opinion that ZHP withheld any safety information from FDA that it was aware of?

A. Yes, it withheld the fact that it never did a full evaluation of its chemical process. That's important to patient safety. So they

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stipulate that they didn't do it, and I don't -- I have no evidence to show that they ever told FDA, "Oh, by the way, we didn't do that." In fact -- in fact, what they did tell FDA and the people they supplied to, they actually say that there were no genotoxic byproducts or degradants in the process, and yet they had never done the work to figure out whether they actually could be there.

Q. Are you of the opinion that the FDA's limitation of resources somehow affected patient safety here?

A. I don't think I form the opinion that at any particular case it's effected patient safety. But the limitations of the FDA are an important context for why it is that it's the company that is responsible for doing all the work, what you were rating out that the FDA may have called "hard." It's not hard work if you do the work, and that's the point.

You have to do the work, take the time, go through the process, understand your process, and make sure that what you're selling is going to be safe and will not put patient health at risk.

Q. Do you know how many times the FDA inspected the ZHP facility during the time period at

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issue in this litigation?

MR. VAUGHN: Objection, foundation.

A. Well, I don't even know all of the time period. Can you tell me your time period? Maybe I can tell you if you tell me what time period is at issue.

Q. Well, do you have an opinion as to what the time period was when Valsartan was -- had impurities of NDMA and NDEA?

A. Well, we don't know the exact time period. I would argue, based on the evidence that I've seen, it goes back at least as far to 2014 in terms of having a process that was in place that, where they were seeing unidentified impurities. But certainly whenever they started using either the -- whenever they started using a process other than the TIN process without doing the full evaluation of their chemical process, that raises the issue of potential contaminants that are nitrosamines.

Q. Beginning at that point until the product was recalled, how many times did the FDA inspect ZHP facilities?

A. I have -- don't have a count off the top of my head. I can't tell you that. If you need to know that, I imagine the number -- I could find that

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in Dr. Bain's report, because I think she goes over the inspections, or maybe it was not Dr. Bain, it may have been Dr. Russ, maybe, I have to go look.
Q. Do you know how many of those inspections resulted in regulatory action?
A. Again, I'd have to go look. That was beyond the scope. I wasn't trying to count up how many times.
Q. In fact, there were multiple FDA inspections during that period, none of which resulted in official regulatory action, isn't that right?
A. Do you mean a warning letter, or are you talking about a recall, what are you talking about?
Q. Any official regulatory action?
A. Well, they had more than one warning letter during that period of time. And I did do a search of the FDA website for that, looking for warning letters. There's more than the one that came out in 2019. But I can't give you an exact number. I'd have to go back and look again at the rather large database.
Q. Can you identify any warning letter other than the 2019 warning letter that had to do with Valsartan?

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A. Well, warning letters that deal with failure of quality systems or violations of CGMPs, and the best one I'm thinking of, there was an older letter that I believe they cited ZHP for a violation of GMPs, that they were looking at the production of a different drug, but if -- other than Valsartan, but if you look at the way that the FDA writes the letters, and I'd have to pull the letter back out, but I believe that the statement they make is not just, "You violated CGMPs for Valsartan or for Losartan," or whatever drug, "You violated CGMPs and you're making adulterated drug products."
Q. FDA never used the word "adulterated" with respect to Valsartan until 2019, correct?
A. It did not deem it adulterated until 2019, that is true. However, if you read my report, I talk a little bit about this.
Q. I read your report several times, Doctor.
MS. MILLER: Do you want to take a break?
THE WITNESS: I'm fine going forward, it's up to you.
MR. VAUGHN: Going for like fifty minutes, is it --

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MS. MILLER: I know, but I need to take a break.
MR. VAUGHN: I thought you were asking us.
MS. MILLER: Thanks.
VIDEOGRAPHER: All right, going off the record, the time is 2:23 p.m. Eastern Time, this is the end of media unit 3.
(Recess taken.)
VIDEOGRAPHER: We're back on the record. The time is 2:40 p.m. Eastern Time, this is the beginning of media unit 4.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. Dr. Plunkett, are you aware of any monograph that references nitrosamine impurities?
A. In terms of an acceptable impurity, is that what you're asking me?
Q. Are you aware of any USP monograph that references nitrosamine impurities in any capacity whatsoever?
A. I'm not aware of one where they are considered an acceptable part of the specification in the compendium, no. And in fact, if you go to the USP website, they have, now, they have a section on

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nitrosamines and pages that talk about how those are unacceptable contaminants and -- or impurities and have been problematic in the industry.
Q. Are you offering an opinion that bioequivalence was lacking here because of the preference of NDMA and NDEA impurities in the Valsartan ZHP API?
A. Not exactly. Want me to explain what my opinion is?
Q. That is not your opinion?
A. That's not the exact opinion. You're not stating it quite as I would. Would you like me to explain? It's in my report. Actually, I talked about the issue of, bioequivalent means two things: Therapeutically equivalent, and pharmaceutically equivalent. And the pharmaceutically equivalent piece that I believe the presence of the NDMA and the NDEA affect the status of the drug as being "bioequivalent," and FDA stated they are adulterated.
By being adulterated, they are not going to be deemed to be bioequivalent, at least that lot, even though the ANDA still exists, and then bioequivalence -- bioequivalence termination has not been rescinded by FDA.
Q. How is that different from what I just

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said?
A. Well, I mean, I'm being more precise and exacting. That's what I'm telling you. The bioequivalent -- the reason I'm doing this is because I have seen documents where people focus on bioequivalent as only on the therapeutic equivalence piece of the puzzle, and it's both.
Q. Are you offering an opinion that pharmaceutical equivalence was lacking merely because the Valsartan API had NDMA and NDEA impurities?
MR. VAUGHN: Object to form.
A. Well, it's not merely because, it's an important -- it's important impurities. It is my opinion that they were not pharmaceutically equivalent when the process used to make them were being -- resulting in the presence of NDMA and NDEA, yes, that's correct, because those are the types of impurities that would not fit at the .1 percent based upon the USP.
Q. Did Valsartan ever have NDMA or NDEA over 0.1 percent?
A. I haven't done that evaluation. I can't answer that. But the .1 percent doesn't apply to genotoxins, so NDMA and NDEA would have a different issue to be -- that they would have to content with.

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If you wanted to make them listed impurities, that's a different issue.
Q. If an impurity of less than 0.1 doesn't have to be identified, how is it possible that it doesn't apply to genotoxins? Is it your opinion that no unidentified impurity in any medication under 0.1 percent is a genotoxin?
MR. VAUGHN: Object to form.
A. No. That's not at all what I'm saying. You're conflating things. So the issue here is, because the process was changed and the chemical analysis or the -- analysis of the chemical process did not look for the potential for genotoxic impurities to result, when those genotoxic impurities do result, that makes that particular product no longer pharmaceutically equivalent.
The Diovan RLD process with the TIN had been shown to be able to be used to manufacture Diovan without the presence of NDMA or NDEA based on the Health Canada results, for example.
Q. But you have not been able to point me to a page in the USP -- in any USP manual or document that says .1 or less of any other individual impurity excludes potential genotoxins, correct?
MR. VAUGHN: Object for form.

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A. Well, they wouldn't have that statement this there. I doesn't make any sense. That's what I'm trying to tell you. I'm trying to tell you that the -- well, if you go for the general -- if you open the general chapter -- general chapters, and I don't know, 5.6, something like that, it's called "Impurities," "Substance Impurities," something like that in the general chapters, and it talks about what to do, and it talks about when you view the process that is not -- was not part of the original process by which the RLD was developed, that you have to look for and understand what impurities are possible. And then that, combined with the fact that genotoxic impurities are a separate issue in terms of how they are handled, that's what I'm pointing to.
So there are potent toxicants, genotoxicants, there can be toxicants that weren't genotoxic that were potent enough that apply the .1 percent standard.
Q. Is there a page in any USP document that says when you are dealing with a potentially genotoxic impurity, you cannot have even less than .1 percent of that impurity in your medication?
MR. VAUGHN: Object to form.
A. I can't tell you if that sentence that

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you're reading is there, but I can tell you that if you read the general chapters of the USP, in combination with the guidance that exists, genotoxic impurities are segregated out as a special group or a special class that are considered differently, where the .1 percent may not be adequate in terms of protecting and making sure that the drug is safe.
Q. All right. So now you're saying there's a place in USP that says .1 percent may not be adequate?
A. The guidance documents talk about where these impurity standards come from, and that's where I'm trying to point you to. If you need me to, let me go into my documents real quick here, and on my computer, and I'll -- but I mean, they are cited. Let me look at my report -- actually, you know what? I think I cite to these in my report. Hold on, just a second.
Q. Hold on a minute, we are short on time and unless you're citing to something that says that genotoxicity somehow cancels out 0.1 percent limit, that's not responsive to my question so I'd like to move on.
A. Well, if you want me to answer the question, I need to look at my report because I do

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have something that I believe is on point or at least relevant to the question you're asking. So if you don't want me to look, I won't. But I do believe that I address this general issue in my report. Want me to look --

Q. You address -- do you address it with a citation?

A. I believe I point to either the guidance documents or to the general chapter, yes. Do you want me to look?

Q. Yes, please.

(A pause in the proceedings.)

A. Okay, so this part of the relevant information that I would point you to is not an actual USP document, but it is the information that is in the Drug Master File from ZHP. And this would be paragraph 54 and I'm -- let me look further.

(A pause in the proceedings.)

A. Well, I'd also refer you to paragraphs 37 through 49 where the company is talking -- "company" being ZHP -- was talking about their recognition of not being compliant with GMP with the presence of nitrosamines and then in addition to that, there's information in -- further on pages 33-34, they talk about this issue of the fact that

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nitrosamines are not to be present in these products, so that's recognition that the monograph is not covering nitrosamines. But if you're asking me for the exact language you're asking me, I don't know, I'd have to go look to see whether the USP had the exact statement that you're asking.

But there are several elements in this case to show that at issue here is the presence of NDMA and NDEA at levels that may be below .1 percent, but they are still a -- an issue with respect to the product being pharmaceutically equivalent to the Reference Listed Product. Different purity.

Q. You did not just point me to any USP cite that says 0.1 percent clearly does not apply to impurities that are potentially genotoxic, correct?

MR. VAUGHN: Objection, argumentative.

A. I told you, for that I would go to the general chapters of the USP where they talk about impurities. I don't have it cited, language out of my report, but those are part of my --

Q. The question I asked --

A. -- if you would like me to pull them out, we could look to that.

Q. That was --

A. But I believe there is something similar

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to that.

Q. But that was the question I asked you when you went to look at your report.

MR. VAUGHN: Objection, argumentative.

A. I understand, and I was looking to see if I had pulled that language out and I had not pulled it out specifically as a quote. But I do know that the general chapters address that issue you're raising.

Q. Let's go back to Exhibit 3 for a moment.

A. Exhibit 3, which one is that?

Q. It will pop up on the screen.

A. Oh, well, I might want to look at it, that's --

Q. It's the August 30, 2018 statement from FDA.

MR. VAUGHN: In that share file Dr. Plunkett, it's listed as Exhibit 3 for you also.

A. I was wondering whether it was an FDA document or it was that article, that's why I was asking.

(A pause in the proceedings.)

MS. MILLER: Are we still on page 2? Okay, I have the wrong page number in my outline.

Q. If you could turn to page 3 here, I

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wanted to point you to this sentence that says, "We estimated that if eight thousand people took the highest Valsartan does, 320 milligrams, from NDMA-affected medicines daily for four years, the amount of time we believe the affected products had been on the U.S. market, there may be one additional case of cancer over the lifetimes of these eight thousand people beyond the average cancer rate among Americans."

Do you see that?

A. I do.

Q. Do you disagree with that statement?

A. I don't agree -- I haven't formed an opinion one way or the other to agree or disagree. This is what you and I spent a lot of time talking about earlier today, where I said that there's an issue -- there's two different issues to consider; there is the issue of an increased risk and there's the issue of whether or not you attempt to calculate, and I have not done that, for individuals what that increase risk will be.

There is risk, regardless of -- even here, they are saying there is risk. There is an additional cancer. So the question is then, how do you handle that as a regulatory agency? They have

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duties, I mean, go to that if you want, but I won't -- I won't draw that all back in, but I talked a good bit about the issue of the context of what the regulatory bodies would do versus what a toxicologist would do when we talk about increased risk.

(A pause in the proceedings.)

Q. Let's move to Exhibit 4. If you look at the third paragraph, it says, "Our analysis of NDMA found that the risk to patients based on the maximum possible exposure appears to be small."

Do you disagree with that statement?

A. I don't agree or disagree with it. I haven't formed an opinion one way or the other. I agree the statement is there, and what FDA has put forward, but I'll -- it doesn't say that there is no risk.

Q. Understood. Are you offering an opinion as to whether or not the risk to patients from the NDMA impurities in Valsartan was small?

MR. VAUGHN: Object to form.

A. I'm sorry, it's beyond the scope of what I was asked to do. But is something I believe other experts are handling in terms of quantifying the risk. I believe there is a risk. I believe there's an increased risk compared to when the product is

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made without it, and that's what's really important. The point is, it's not supposed to be there. FDA says that it's unacceptable, you need to take it out, you need to make it -- you can make it, we know it can be made without it, and that's what the important -- the important finding is.

FDA only has to deal with these things on, with an ongoing kind of a crisis in terms of drug shortages and different things and so it's adapting and learning and it's making statements over time.

Q. All right. I appreciate that speech, but really I just want to know whether you think the risk is small or --

MR. VAUGHN: Oh, don't be argumentative with her. And -- you made the comment you made.

MS. MILLER: Brett, do not interrupt --

MR. VAUGHN: Jessica --

MS. MILLER: -- no, Brett, you cannot interrupt my questions, that's rude.

MR. VAUGHN: Okay, don't interrupt her either.

MS. MILLER: I didn't interrupt her.

Q. Dr. Plunkett, you have no opinion on whether or not this risk is small?

MR. VAUGHN: Object to form.

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A. I have not quantified the risk.

Q. Okay.

A. As a result of that, as a result of that, that's how I would make a judgement over small or large.

However, I do believe that there is an increased risk for any individual who would have taken these drugs with NDMA and NDEA, based on the fact that there is no level identified without risk.

Q. And that opinion applies even if the person only took one pill, correct?

MR. VAUGHN: Objection.

A. It could apply, yes. It depends on the person and the situation. But certainly, the issue is, I'm not doing case-specific individual exposure assessment. I'm talking about this in the context of whether or not these products generally posed a hazard to the patients who were taking it, and whether or not there was something that could have been done about it.

And certainly we know that the product could be made without these impurities.

Q. If we could turn to page 19 of your report, Exhibit 1?

A. Were you in paragraph 30?

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Q. I am. Do you see the language in bold italics?

A. Yes, that I highlight, which is the quote, yes?

Q. Can you read that sentence?

A. "However, identification should be attempted for those potential impurities that are expected to be unusually potent, producing toxic or pharmacologic effect at a level lower than .1 percent."

Q. Do you know whether NDMA or NDEA produces toxic or pharmacological effects at a level lower than 0.1 percent?

A. Yes, based on the cancer risk assessment that you would do, where there is no safe level of exposure. So the issue would be, NDMA and NDEA would be identified as carcinogens, as carcinogens and genotoxins. They are compound where you can't identify a no-risk level.

Q. And is -- are you saying that "can't identify a no-risk level" is the same thing as "expected to produce toxic or pharmacologic effects at a level lower than 0.1 percent"?

A. Yes, when you're talking about a carcinogenic agent. Because carcinogenic agents, you

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couldn't tend to regulate based like you do non-cancer agents. Carcinogenic agents generally, when, as FDA has said, they shouldn't be there, it's unacceptable, it needs to come out, and that's the issue.

Q. Have you done the work necessary to determine whether NDMA or NDEA can produce toxic or pharmacological effects at a level lower than 0.1 percent?

MR. VAUGHN: Object to form.

A. Are you -- I don't quite understand what your asking. Are you asking me -- let me ask a question. Are you asking me, did I do a quantitative risk assessment? I've already told you I did not. Others in -- other experts in the litigation are doing that.

But regardless of whether it's at a level lower than .1 percent, agents that are genotoxicants, or carcinogens, are considered to pose a hazard, increase the risk, have the ability to, in some individuals, produce a toxic effect at a level lower than that because you can't extrapolate to a level that is "without risk."

Q. Can you point me to a single piece of literature that states that NDMA or NDEA can produce

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toxic or pharmacological effects at a level lower than 0.1 percent?

MR. VAUGHN: Objection, vague as to what 0.1 percent is referencing.

MS. MILLER: It's in this quote.

A. I would read this as .1 percent, which would be a thousand parts per million. So can I find a study? Possibly. Have I looked for it? No, because when you talk about carcinogens, you don't try to identify a threshold. That's what I'm trying to tell you.

Now, if you're going to talk about, is there a toxic effect that might occur at a level, only a level higher? It's possible. But the issue is, the overriding concern in terms of the safety of exposure to NDMA and NDEA, is the carcinogenic and genotoxic potential, not other types of toxicity which might occur at higher levels. I point you to the discussion of this in the NTP, ROC document that I cite to, and also all of the studies that are gone through as part of the IARC evaluation as well.

Q. But you don't know whether any of those studies actually found a toxic or pharmacological effect at a level lower that 0.1 percent?

MR. VAUGHN: Objection vague.

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A. If you defined .1 percent in parts per million, I'm sure you do. But I can't point to it, because I -- I'm telling you, if you want me to do that, it's beyond the scope of what I did, trying to do a dose/response, quantitative risk assessment for things other than cancer, or even a specific dose or specific exposure pattern that would lead to an increased risk of one in a hundred thousand versus one in ten thousand versus one in a million. I have not done that. Others in the litigation are doing it, and they would be able to provide you that answer to that question.

But I'm telling you, I'm sure you can find this information in -- in some of the recent sources that I have cited, but it was beyond the scope of what I did.

Q. Do you know whether DMF reached a boiling point during the manufacture of Valsartan?

MR. VAUGHN: Objection, foundation.

A. That was beyond any scope. I don't recall, but that may be able to be found in the chemist's report. I just don't recall.

Q. Do you know whether DMF has ever been described to decompose in the circumstances in which it decomposed in Valsartan?

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MR. VAUGHN: Objection, vague, foundation.

MS. MILLER: I can ask the question differently if you don't understand it.

A. Well, I'm not the chemist so the question you're asking I think is beyond the scope of the opinions that I have formed. But I would -- I would -- maybe we should be careful to make sure that when you're saying DMF, you mean the chemical, not the drug master file. For the purposes of the court reporter, there's that abbreviation is used two different ways.

Q. I don't think any Drug Master File is decomposed here, so I think we are all understanding what we're talking about.

You say it's beyond the scope of your opinions, but you do offer the opinion that it has been known, right?

MR. VAUGHN: Objection, norm.

Q. If you offer the opinion that it has been known that DMF can decompose in certain circumstances, right, is that one of your opinions?

A. It's -- it's my -- it's my opinion that it was known before this product was -- you had this issue with this product, but if they had done a

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chemical risk assessment, they would have been able to understand the potential for formation of genotoxic impurities like the nitrosamines. I, however, did not attempt to do an analysis or root cause analysis or even a full chemical analysis of their processes.

Again, that was what the chemist has done in this case. That was beyond my scope.

Q. Since you do offer an opinion that it was known that DMF could decompose in certain circumstances, can you tell me what those circumstances are?

A. That was beyond the scope of what I did. I'm pointing to the literature. I think you're taking that from the literature when I talk about the literature section, I believe. And those papers would speak for themselves, I believe. And I'm citing to them on the issue of, there was evidence to show that before 2012, there was chemical information that the company, ZHP, could have identified if they had done a literature search and attempted to look, if they didn't understand that process, could have gone to the literature to figure out if there was something about their intermediates or -- or process ingredients that would pose a risk of genotoxic

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impurities.

Q. For that opinion you cite an Australian textbook which you found in prior depositions in this litigation, correct?

A. It was something that was cited and testified to in deposition testimony in the litigation, that is correct.

Q. Have you ever seen that Australian textbook before this litigation?

A. You already asked me that and I said I had not, I said I had not seen that textbook, it's not one that I have in my library.

Q. You testified earlier today that ZHP did not pursue complaints about potential peaks, is that correct?

A. I don't think that's exactly what I said. I think I said, I think what I said is consistent with what's in my report, where I talked about the fact that they had, were on notice or had reports of impurities that they apparently did not resolve, in other words, if you look at the testimony. So am I going to find that in my report for you?

Q. Where did you use that language, "Did not pursue," is that still your opinion this

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afternoon?

A. If you define "did not pursue" in terms of "did not resolve," that is true. I had no evidence in this case to show that they attempted to identify what those impurities were.

Q. Let's turn to --

MS. MILLER: -- Alex, what exhibit are we up to? I think six or seven.

Q. Okay, let's go to tab 43 and mark it as Exhibit 6.

EXH (Plunkett Exhibit 6, e-mail chain Bates numbered ZHP00492652 through 92659, marked for identification, as of this date.)

Q. Dr. Plunkett, this is an e-mail train from September 2017. Have you seen it before?

MR. VAUGHN: Would you let me know what this is --

MS. MILLER: I'm just asking if she's seen it before, then I'll let her read it, obviously.

(A pause in the proceedings.)

A. I need to see the -- further into the e-mail, you know, because -- is it up where I can take a look real quick, tell you if I've seen it?

MS. MILLER: Why don't we follow that procedure of going off the record --

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A. I don't necessarily need to read it carefully. I just need to look at the whole document to tell you whether I --

Q. I'm going to ask you some questions about it. I thought I could --

MR. VAUGHN: Can you guys just put it into the share file like the procedure is so she can look to see if she's seen it --

MS. MILLER: We did. We did, Brett.

MR. VAUGHN: I just asked if you guys would tell me when you have. I'm refreshing it and I don't -- okay.

THE WITNESS: I didn't see --

MR. VAUGHN: It just went in.

MS. MILLER: Alex is doing it as quickly as he can.

MR. VAUGHN: Sorry, Alex.

A. I need to be able to look at it so I need you to stop share, I don't know how to get to it otherwise.

Q. Okay.

MS. MILLER: We're going to go off the record because it's eight pages for you to read it, and then just let me know when you're done.

VIDEOGRAPHER: Going off the record.

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The time is 3:13 p.m.
(Discussion off the record.)
(A pause in the proceedings.)
VIDEOGRAPHER: We're back on the record. The time is 3:17 p.m.
Q. Dr. Plunkett, now that you've read this e-mail chain, have you seen it before?
A. I didn't recall this one, but within a time period where I had seen some, and I went back and compared it with my reliance material list, unless it has a different Bates number than you have on the bottom, I don't know if I've seen this.
Now if it was an exhibit to a depo I've read, then I just may not remember it.
Q. This is an e-mail exchange between ZHP and Aurobindo, correct?
A. Yes. That's correct -- well, yes, that's correct.
Q. Is it correct that Aurobindo is raising questions about unknown peaks?
A. Can you just show me where it is you're referring to? I assume it's in the later pages of the document.
(A pause in the proceedings.)
Q. If you look at page 2656, paragraph 2.

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A. And as it relates to the residual solvents they are asking some questions, yes.
Q. Based on this e-mail chain, does it appear that ZHP pursued these unknown peaks to determine what they are?
A. I -- I don't recall whether -- the testimony around this to know whether that is true for all the peaks, but certainly, there is a discussion in this part of the e-mail that they were answering some questions, that is true.
Q. In fact, if you look at page 2654, each of the peaks is listed, right? And then it says, "HH." Right?
A. Again, I don't recall this document so if you want me to confirm that it is a complete discussion or -- I would need to see accompanying information with it. I don't recall this document, so --
Q. I understand. But I'm asking you reading it now, do you see the "HH:"?
A. I don't see "HH." Where are you referring to? Okay.
Q. So ZHP is saying here, "We did a study and we identified unknown peaks and here is the explanations," is that correct?

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MR. VAUGHN: Objection, that is not what it says, it says "identified some unknown peaks."
A. So they didn't identify everything. And in fact, they mention -- I was going to say they mention that the peak at 13 they say they didn't see, but I -- I don't disagree with you, this is an e-mail discussing some questions from Aurobindo.
Q. Does this e-mail suggest that ZHP did pursue unknown peaks?
MR. VAUGHN: Objection, form.
A. Well, there is other testimony that indicates they did not always pursue unknown peak questions from their -- their customers, or the people they were supplying to.
Q. In this instance, did ZHP pursue these unknown peaks?
MR. VAUGHN: Object to form.
A. I can't tell you the complete level of what their pursuit was, but I don't disagree with you that they are describing some results for some peaks in a question that was raised by Aurobindo in that case, that is correct.
Q. I mean, if you look to the next page, 2653, because with e-mail chains, you go up, not down, they say, "Regarding R214.5, we need little

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more time to do further tests." Correct?
A. You have read that correctly, yes. By "MS," yes, that's the --
Q. And it suggests that ZHP was doing testing to understand these unknown peaks, correct?
MR. VAUGHN: Objection, form, foundation.
A. Again, not having seen the context around this, I can only tell you what the e-mail says and I would agree with you this particular e-mail is showing that at this particular point in time from Aurobindo, they were investigating some unknown peaks.
Q. In preparing --
A. And use the residual solvent methods.
Q. -- in preparing your report, did you ask to see all occasions in which ZHP followed up to pursue claims of unknown peaks?
MR. VAUGHN: Object to form.
A. I don't think I did, no.
Q. Why not?
A. I thought that was beyond the scope of what I was doing in terms of an analysis -- I wasn't doing a GMP compliance analysis, in the way other experts were doing. So it was my understanding that

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other experts were following up on many of these interactions with other companies.
Q. But you're offering an opinion that ZHP did in the pursue claims of unknown peaks, correct?
A. There certainly is evidence that they did not always pursue, that is correct, based on other documents that I have seen.
Q. Is this document relevant to your opinions?
A. Well, it would provide an evidence that in this particular case, for this particular question, they were following up, but they weren't following up based upon some of the other information that I have seen.
Q. And what is that other information?
(A pause in the proceedings.)
A. So it's the deposition testimony of Dr. Li that I discuss in paragraph 48.
Q. Paragraph?
A. Forty-eight. In my report.
Q. Okay.
A. So I'd have to pull this out.
Q. Okay.
A. What I'm citing to you what I would be relying upon for that opinion, or that statement

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actually.
Q. So that statement just relies on Dr. Li's testimony, correct?
A. Well, the documents that accompany it, too, yes.
Q. Are there documents accompanying those pages of testimony? It's only one page, right?
A. 261 to 265, page 268, it's the discussion that's going on through here. So I'd have to go pull it back out, but...
Q. Okay. And let's turn to tab 46, which would be Exhibit 7. Okay, we're going to mark Exhibit 7.
MS. MILLER: Don't worry, Brett, you're going to get it.
MS. VAUGHN: Thank you, Jessica.
MS. MILLER: Forty-six.
EXH (Plunkett Exhibit 7, e-mail chain Bates numbered ZHP02118712 through 8731, marked for identification, as of this date.)
Q. Dr. Plunkett, do you know if you've seen this e-mail chain before?
A. I'd need to compare it with the Bates number, can you put that up for me?
Q. Okay. So this is another long one, so

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why don't we go off the record for you to read it because I will have some questions about it.
VIDEOGRAPHER: All right, going off the record. The time is 3:26 p.m.
(Recess taken.)
VIDEOGRAPHER: Stand by, just a few moments. We are back on the record. The time is 3:31 p.m.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. Dr. Plunkett, having had some time to take a look at this, do you recall whether you read it before?
A. It is on my reliance list. I don't recall reading it. And a lot of what's covered in here, a lot of it would have been something that I felt would be beyond the scope of what I was doing but were more relevant to the GMP expert and the potentially the chemists, because it deals with the issue of validation. But it does talk about unknown peaks in the very top e-mail. It indicates that the customer is asking some questions about things that haven't been resolved yet.
Q. What's going on?
A. The customer, based on what I'm saying

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about again, this is not a document I cited to in my report, so I'd have is to go back and look at the deposition testimony around this as well.
Q. In this document, is Glenmark asking ZHP to identify certain unknown peaks?
A. It's -- Glenmark is -- in the top e-mail, it's a series of e-mails about impurities and peaks and then at the top e-mail, Francis Dsouza from Glenmark is asking whether or not -- these are some things that haven't been resolved, so they are sore points.
Q. Um-hum. And if you look --
A. That's all I can tell you because I don't recall this document's discussion in any of the -- in the depositions, I'd have to go back and look.
Q. If you look to page ZHP02118713, which is the second page of the document, it's an e-mail from ZHP in which he says, "Dear Francis, we investigating the same on our side," correct?
A. Yes, you've read that correctly. But this is, you -- that's all I can tell you. Because I haven't -- I'd have to go look at the deposition testimony for the context for this one.
Q. Based on this document, does it appear

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that ZHP was following up on this issue?
A. Well, they hadn't totally followed up by the last e-mail in the chain, but they certainly were doing some work, that is true.
Q. And what's the date of this e-mail chain?
A. I think it's 2016, December. I don't know when the first one starts, whether it was in November, but it certainly is December.
Q. All right. And now let's look at tab 48, which we're going to mark as Exhibit 8.
EXH (Plunkett Exhibit 8, e-mail chain Bates numbered ZHP02118681 through 8711, marked for identification, as of this date.)
Q. And this is dated April 2017, correct?
A. I don't know, I don't have it yet.
Q. Tab 48 is an e-mail chain, and the top e-mail is dated April 20137, correct?
A. I'm waiting for you to upload it so you can look at it.
Q. Can you see on the computer screen that it's dated April 2017?
A. Yes, April 20th, the first page I see that.
Q. And the -- and at the top of the page,

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in terms of the "re" line, it says, "Valsartan from Huahai -- Impurities and Unknown Peaks," correct?
A. That's the title, yes.
Q. And it's the same title as the last e-mail chain we were looking at, correct?
A. I don't remember, but I think it -- well, it looks like it's involving Glenmark, so my guess is it's somewhat related. I don't know for sure, I'd have to compare them.
Q. And do you recall whether you reviewed this e-mail chain and its attachment in preparing your report?
A. I don't recall it, but I can look and see where it's listed, so if you want me to look in my appendix C.
Q. I did not find it there, for what it's worth.
A. So if it's not in appendix C, then it's not what that I recall, no.
Q. Would you like to read it before you answer questions about it?
A. Surely, absolutely, because I don't -- the question -- this one is 29 pages long.
MS. MILLER: Lets go off the record again. I'm so sorry, court reporter, for all the

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on-and-off.
VIDEOGRAPHER: Going off the record. The time is 3:35 p.m.
(Recess taken.)
VIDEOGRAPHER: We are back on the record. The time is 3:39 p.m.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. Just is to reorient us, we're looking at Exhibit 8. Exhibit 8 is an e-mail chain between Glenmark and Huahai. Are you familiar with what Glenmark is, Dr. Plunkett, is that company familiar?
A. You asked me that, and it looks like they are a pharmaceutical company. But I don't know what their relationship is with ZHP other than they are asking questions about materials used, they are actually talking about raw materials used in the manufacture of Valsartan.
Q. But this is a follow-up on the e-mail chain we looked at earlier regarding unknown peaks, correct?
A. Yes, but this one actually gives more context which is a little helpful. So, you know, the first ten pages or whatever were the same, if you go to the very first page of this exhibit, and the

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second page of the exhibit, and down to page 685, you get, the last three numbers, you get a little bit of context of what was going on.
Q. There is an attachment to this document, in which ZHP has set forth the identification of each impurity, correct?
MR. VAUGHN: Objection, form.
A. I don't know what you're talking about. They indicated that there were certain things they have not resolved. This is raw material issues carryover.
Q. If you look at the last three pages of the document, there is an attachment to the document that's a table and for each impurity, there is a column that says, "Origin of impurity," correct?
A. I can't see it on the screen. If you would go to the last three pages, I can maybe answer your questions.
MS. MILLER: 709.
(A pause in the proceedings.)
Q. Well, you can't look at it in your shared file?
A. If you stop sharing screen so I can have access to my screen.
Q. One second.

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A. So you want me to look at my screen?
Q. Hold on, Alex is dealing with the technological problem.
(A pause in the proceedings.)
MS. MILLER: Alex is having a technical difficulty, we're going to go off the record for two minutes.
MR. VAUGHN: It's just two minutes, let's just -- are we really --
MS. MILLER: What if it turns into four and my time is waiting, so yes, please.
VIDEOGRAPHER: Mr. Vaughn, you're agreeing?
MR. VAUGHN: That's fine.
VIDEOGRAPHER: Okay, going off the record, the time is 3:42 p.m.
(Recess taken.)
VIDEOGRAPHER: We're back on the record. The time is 3:57 p.m. Eastern Time. This is the beginning of media unit 5.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. Great. Dr. Plunkett, sorry about the technical difficulties, that seems to be the theme of the day. We have now fixed Exhibit 8, so we are

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reintroducing Exhibit 8 which is an e-mail chain that says at the top, "Re, re, Valsartan from Huahai, Impurities and Unknown Peaks."
The last-in-time e-mail, which is on the first page, is April 20, 2017, and there is an attachment to the e-mail which is the last two pages right here. Those highlights are not -- we did not make those highlights, that's how we received the document. Just to be clear.
And before we went off the record, I was asking you whether the attachment to the document includes an explanation for each of the impurities identified by Glenmark.
A. Did I see the second -- if there's two pages, may I see the second page?
Q. Of course.
(A pause in the proceedings.)
A. I can't confirm about looking back at the rest of the e-mail whether there were only ten peaks in question, but I would agree that for at least ten of these, they are giving information.
Q. And there's a third page, I apologize.
A. So, okay.
Q. And that goes to twelve peaks.
A. So same answer, that I would say twelve;

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in other words, I would need to confirm that there were only twelve peaks being raised but I agree with you that there is a table that is talking about twelve peaks.
Q. So you would agree that in this instance, ZHP pursued the origin of twelve peaks identified by a customer, is that fair to say?
MR. VAUGHN: Object to form.
A. Go back up, please, to the next page. Next page, please. I'm trying to read what the origin says.
Q. Um-hum.
A. So state your question again, please, I'm sorry, I don't mean to be rude, please.
Q. Based on this e-mail chain, did ZHP follow up in an attempt to determine the origins of the impurities identified by Glenmark?
A. In reading the entire, not just this -- reading the entire e-mail, which isn't just this table, it's clear that there were questions being raised by Glenmark about -- about the Valsartan product materials. They did do some investigation. It's not clear to me, however, that they answered all questions at all times. But certainly, in here, they are answering some questions.

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However, this entire thing that we see here, if you go to page ending in 685 on this e-mail string, it's interesting that ZHP is admitting that they didn't always follow the same types of procedures because FDA wasn't so picky. I thought that was practically interesting. In other words, it's clear that not necessarily over the years has ZHP always done the same thing.
Q. Now, in your expert report, I believe you said you cite the Li deposition on pages 261 to 267 for your opinion that ZHP did not follow up on unknown peaks, correct?
A. I say that ZHP had received complaints from customers beginning in 2014 of unknown peaks identified through chromatography that ZHP failed to investigate, yes, that's what it says.
Q. And your basis for "ZHP failed to investigate" is the testimony of Li?
A. Yes, there was a company, a corporate witness brought in to answer questions about their procedures and process.
Q. Okay.
MS. MILLER: So let's introduce as Exhibit 9, Min Li's deposition.
EXH (Plunkett Exhibit 9, transcript of

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deposition of Min Li, Ph.D., marked for identification, as of this date.)
Q. Do you have a hard copy of that with you today or not?
A. No, I didn't, it's too much to print out, so saving some trees.
Q. I think you said you were looking at pages 261 to 267, correct?
A. Lets see.
MR. VAUGHN: Objection, misstates the record --
A. When I read to 261 to 265, and then 268 as well.
Q. Okay, great. Can you show me where Min Li says, "We didn't follow up on complaints about unknown peaks"?
A. So it would -- could you -- well, I'm going to need to scroll through, so do you want to put this up so I can really quickly look? It won't take but a minute, or is this an exhibit that you're marking or not?
Q. We already marked it.
A. So let me go, if you let me out, it would take but a minute. I don't think I need to stop the clock.

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Q. If it's just a minute, that's fine. I only try to stop the clock when it's more than five to ten.
(A pause in the proceedings.)
A. So starting on page 261, you have that -- you had it up at line 17, where he's, that's where the initial question comes. So then you have to scroll through. And he says, "Yeah, for some, you now, during the later stage of the investigation, you know, yeah," and he talks about Novartis, Sun Pharma at the time, keep going --
Q. I'm just asking where does he say that they didn't pursue or follow up on the complaints?
A. I think that's the answer to the question, it starts on page 261.
Q. What are the words, can you just show me the words where he says, "We didn't follow up"?
A. He's asked that question, and he responds, "Yes." So when the question is being asked -- go to the question. "You're aware that starting in 2014, complaints came in on a regular basis asking for answers, you do know that there were multiple complaints and requests for information." So that's the acknowledged to, yes, he's aware that were complaints in 2014.

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Q. That's not my question.
A. No, but I need to go further, okay? So that's the first part of the statement. All right. So now I need to -- let me go back and look for the second part. I'll need to be able to get back to the document again, please. Thank you.
(A pause in the proceedings.)
A. Unfortunately, you have to read through all of these pages, he's answering questions about -- and he qualifies them at different times where some of those questions were treated like technicals, some of them, they couldn't figure out, they didn't know what they were, they didn't identify them.
So this is the basis, the testimony that I'm pointing to is throughout this entire exchange and unfortunately, because it is English as a second language, sometimes it's a little stilted to read.
Q. If we could turn to page 266, lines 16 through 20, can you read that to me?
A. I think -- you're starting with "I think"?
Q. Um-hum.
A. "I think, you know, in the end, you know, we -- for all the concerned peaks, you know, I think, you know, we were able to find the identity or

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the potential sources."
Q. Do you quote that in your report?
A. These four lines, no. But again, if you read his deposition, and the -- and the questions that were coming in, it's clear that he's talking about -- about not having followed up on everything, but he is saying that they did identify potential sources, which would be, I'm not saying that they didn't ever identify potential sources, I just know that they didn't follow up and they never went through the process to determine whether or not their process was producing something that they should be looking for.
Q. He says, "For all of the concerned peaks we were able to find the identity." Correct?
A. Well, "Concerned peaks," yes, but that doesn't mean every peak.
Q. All the ones that people expressed concerns about, right?
A. Again, I don't know what to tell you but when I read this section, to me this section as telling me that they were acknowledging that they had received complaints of unknown peaks; and it's my opinion, based upon all the documents I reviewed, that they indeed failed to investigate all of those.

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Q. Is there a single sentence here in which Min Li says, "We did not follow up or pursue claims of unknown peaks"?
A. On these pages we're looking at, I don't see that language. That is your quoting it.
Q. But those are the pages that you cite for the opinion that ZHP did not follow up on unknown peaks, correct?
A. Yes, that's correct.
Q. And sitting here today, you can't actually find that language, correct?
A. The language as a quote, no. But again, if you read his deposition, and look at his discussion here of what they are or aren't doing, he talks about not necessarily having it; but go back up further, in the -- in the -- he says, "I don't know" -- okay. Unknown peaks, he says, "That's a correct statement," right? He says, "Okay, as I indicated, no, it was not informed, you know initially, and some of this conversation, you know, I said I was being consulted or I was trying to help them and find out the identity."
Q. Does that say ZHP did not follow up?
A. I'm saying to you that it's my opinion, based on this testimony plus other documents in the

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case that they did not follow up on all of the unknown peaks, that's --
Q. Well --
A. For no other reason, you know, you have the Novartis issue and Novartis raised questions where Novartis had to do work to identify the peak. Instead what the company did is, said, "It's not a problem," and Novartis found the peak.
Q. When you say "plus other documents in the case," are there other documents in which ZHP has testified, an ZHP witness has testified that ZHP did not follow up on unknown peaks?
A. Let me look.
Q. I only cite --
A. I know, but let me look at other -- at some of the other things that I cite to.
So the -- I'll point you to the second half of paragraph 48 for sure, where that was what I was just talking about, was the idea of the -- that's the discussion of the NDMA from Novartis, that Novartis identified, and if you read the documents around that time period, when Novartis was asking questions, it's clear that they were not getting a response from -- ZHP was not responding, and -- and Novartis was the one who was being forced to

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determine what that that peak was.
Q. But that's not what we're talking about, right? We're talking about that ZHP received complaints from customers beginning in 2014 of unknown peaks identified through chromatography, that ZHP failed to investigate. And what you cite for that is Dr. Li's deposition, correct?
MR. VAUGHN: Object to the colloquy.
A. I cite to his deposition and then if you go on and read through the paragraph --
Q. I'm just --
MR. VAUGHN: Do not interrupt my expert. This is twice. Want to ask your question again?
A. No, if she'll let me finish, I'll go ahead. And what I was going to say is, further in this -- this wasn't Dr. Li's written but further in this paragraph, I am discussing the evidence in the case which is discussed in Dr. Li's deposition, about the NDMA with Valsartan, and the documents that in that -- that surround that, and I'd have to pull this Prinston document out.
But there's other documents that have the back-and-forth and it's clear that Novartis is the one that was having to push the company and then it gives up and goes and does the identity, and then

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lets the company know that it had identified NDMA, and "the company" being ZHP. So Novartis was doing an investigation, a full investigation to find the peak and not giving up even if it had to do additional types of testing to determine what it was.
Q. When you say ZHP failed to investigate, you cite on pages 261 to 265 of Dr. Li's deposition in that sentence, correct?
A. At the end of that sentence, that's what I cite, that's right.
Q. And you do not cite page 266, where Dr. Li says, "I think you know in the end, you know, for all the concerned peaks, you know, I think you know we were able to find the identity of the potential sources." You didn't cite that, right?
MR. VAUGHN: This is getting quite argumentative, especially with your tone.
A. I did not cite specifically the last page, that is correct. But again, if you read the rest of my paragraph in this section of my report, I am referring to the entirety of the evidence in this case, which includes what went on with the questions raised by Novartis, as well, which is also one of its customers.
Q. You testified earlier about a 2017

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e-mail from Jinsheng Lin, correct?
A. I said I have one discussed in my report, yes. Is that what you're referring to?
Q. You testified about it earlier and you said there was a 2017 e-mail.
A. Yes, that's in paragraph 47.
Q. Do you know whether that e-mail is written in English or Chinese?
A. There's an English translation that was provided as part of the deposition testimony which is where I -- it's -- that's the version of the document that I reviewed and relied upon. They had a Chinese version and then they had a translated version.
Q. Are you aware that there are multiple translations of that document?
A. I am aware of the version that was used as part of the deposition, which typically in my experience is a version that I can rely on as being an accurate reflection of what the e-mail says.
Q. Did you read on the report of ZHP's chemist expert, Fengtian Xue?
A. Is this the report of this individual?
Q. Um-hum.
A. Yes, I have read that.
Q. You read Dr. Xue's fluent in Chinese?

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A. I don't know him. I know he states that he is, that's correct.
Q. Are you aware that he lived in China for the first 25 years of his life?
A. I don't know. I don't recall what his CV showed, but my answer to this line of questioning would be, in the deposition, when the document is used with the employees of ZHP, nowhere does anyone correct the translation around that document, that's all I can say. I rely on the translations as part of the exhibits to depositions all the time.
Q. How did Dr. Xue translate the e-mail?
A. I don't recall, I'd have to pull his report back out. They certainly didn't retranslate all of these sections that I have looked at, I don't believe.
Q. Do you recall an e-mail in which Novartis commented that ZHP support throughout the process of identifying NDMA had been exceptional?
A. Would you show me what you're referring to? I don't recall that. If you'll show me the e-mail, I'll let you know if I've seen it.
Q. Do you recall whether you cited in your report an e-mail in which Novartis stated to ZHP that its support had been exceptional during the process

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of identifying the --
A. I don't cite to it, I don't think. It may be in my reliance material. If you could tell me whether it is or not, or show it to me and I'll confirm if it's there or not.
Q. I'm just asking --
A. I already answered, I said I don't recall. It's possible it's one that I just don't recall.
Q. Are you offering any opinions about ZHP's handling of the recall?
A. No, that was beyond the scope of what I did. However -- however, I do have opinions in my report where I talk about the issues that led up to the recall, which is having to do with the fact that in is something that shouldn't have -- shouldn't have occurred if ZHP had done its work to start with.
Q. Are you offering any opinions about any of ZHP's conduct from the time of the recall forward?
A. I don't believe in my report I'm addressing that, no. Although I would say that the one thing I do address after that time period has to do with the 2019 letter from FDA where they actually are letting ZHP know that indeed, their product was adulterated.

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Q. Are you offering any opinions of ZHP's responses or conduct in the face of the FDA's warning letter?
MR. VAUGHN: Object to form.
A. So that was beyond the scope, I believe, of what I did; so, no. I don't think you'll find that in my report.
Q. Are you offering an opinion as to whether ZHP's corrective actions were adequate?
MR. VAUGHN: Object to form.
A. So be more specific what you mean by "corrective action."
Q. The corrective action ZHP took in response to the 2018 warning letter.
A. So to answer that fully, I'd have to pull out whatever letter it is that you're saying that they did.
Q. I'm asking you if you're offering an opinion in this litigation about ZHP's corrective actions in response to the November 20189 warning letter.
A. In order to answer that fully, I need to see the letter you're referring to in order to see whether or not anything in that letter is directly addressed by the opinions I have expressed, that's

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all I'm saying to you. I don't recall citing to that letter but some of things that I discuss may indeed be relevant to what is in that letter.
Q. Well, I'm just asking if you have any opinions in this litigation regarding the corrective actions that ZHP took after November 2018 in response to the FDA warning letter that we've discussed earlier today?
MR. VAUGHN: Objection, asked and answered.
A. Again, in order to answer that question fully, I need to see the letter, which I don't recall, and whether or not any of the opinions in the paragraphs are expressed where I talk about the responsibility of the company and those kinds of things and what they were required to do, whether there was any -- anything there that would answer your question. And I can't do that without looking at the letter. So if you put up an exhibit, I can take a quick look.
Q. Did you just say you don't recall the November 18 warning letter?
A. I don't recall what response. You asked me about the corrective actions in response but I don't recall that. I'd have to pull that up.

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Q. If a company engages in CGMP violations, does that mean that its products are adulterated?
A. The definition that is provided within the regulations, CGMP violations lead to adulterated products, yes.
Q. Does it matter --
A. There's different types of standards for what is adulterated; but certainly, that could be, yes.
Q. Do all CGMP violations result in a product being adulterated?
A. I just said to you it depends. Again, it's consistent with the definitions. In fact, the letters that are -- have been issued in this case, that talk about adulteration or being adulterated, are linked to CGMP violations, but certainly there are different types of CGMP violations that may or may not result in a finding of -- issuing of a warning letter that deems a product adulterated.
So it depends, that's what I'm saying to you. It just depends. I'd have to look at each situation. In this case, yes, the CGMP violations are what is cited by FDA, as a basis for its finding of adulteration and it points specifically to the presence of the NDMA and NDEA impurities in the

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product.
Q. Which types of CGMP violations do you believe lead to adulteration?
A. Things that have to do with the purity, identity, strength of the the product, violations that lead to -- when I say "identity," they are adulterated products that may end up having something in them that isn't supposed to be there, not an impurity, but an active ingredient that carry a -- another active ingredient along, like having Fentanyl in a morphine tablet would be an adulterated product because of the issue of the potency and the danger that's posed there.
Certain kinds of GMP violations, however, such as recordkeeping violations, or minor ones, may not lead to a warning letter and a finding of adulteration. It may -- instead, they may be written up in a 483, without a warning letter. So a 483 would be issued, and it may or may not be accompanied by a warning letter that would deem the products adulterated because of GMPs.
Q. Is it your opinion that any time a generic drug has an impurity that the manufacturer did not identify through its risk assessment, that there was a CGMP violation?

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A. I think that depends on the situation. What type of impurity it was, is it a potent toxicant or a genotoxicant, it's -- let's say, that's a case-by-case question that you would need to answer based on the situation in hand.
In this situation, indeed, that was an issue.
Q. And when you say these are case-by-case situations, is there some sort of FDA document that sets out what the standards are and what the criteria are for -- in other words, are your opinions based on any sort of document, are they based on specific FDA standards? What are your opinions based on that your offering me right now?
MR. VAUGHN: Object to form.
A. Repeat your question again. But not the question you just asked, the first question, I'm sorry.
Q. I'm not sure what you mean by "repeat your first question," I --
A. You asked me a question, and I thought I answered it, and then you asked a clarifying question. So go back to the original question, and let me make sure I am clear, I am certainly -- because I think you're misunderstanding me because I

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absolutely am saying that there are certain standards. The question is, are there certain FDA standards in terms of GMP violations where they talk about the issues of seriousness and non-seriousness of violations? There's a question-and-answer document that's out there and a guidance document talks about that, is that what you're asking me?

Q. I'm asking, is there a place I can go for FDA regulations to understand your views about when a CGMP violation results in adulteration?

MR. VAUGHN: Object to form.

A. You can go to my report and the actual specific language and the definition of what's an adulterated product, where it mentions that. So that's on page --

Q. That's not what I'm asking.

A. Yes, it is. You asked me for where you go to, and time telling you, I lift it right out of the definitional language of FDA for what's an adulterated product, and it pounds on language around good manufacturing practice. So that would be part of my answer to you, and I'm looking for the section of my report where I note that.

There, on page 25, I go to the law itself, it's 21 U.S.C. 351, that talks about the U.S.

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drug law that addresses what makes a drug adulterated, and gives the definitions for it right there. And I've highlighted some of it that I thought was particularly -- at issue in this particular case. It talks about conformity with good manufacturing practice to ensure that the drug meets the requirements as to safety and has the identity, strength and meets the quality and purity characteristics.

Q. Is this all the FDA documents that you're relying on with respect to your opinion that some CGMP violations lead to adulteration and some don't?

A. No, there's warning letters on the FDA database, when you do a search for adulteration, that you'll find that the majority of the time, they are citing to CGMP violations. There is -- there are the guidance documents that talk about GMPs and what particular parts of the GMPs exhibit and why. I think there was a question-and-answer document. Yes, there's a question-and-answer document that I cite in my report called, "Questions and Answers on Current Good Manufacturing Practice Requirements." And there is a -- there are sections there that talk about that, questions back and forth.

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So I don't know what else to tell you, and I think I actually, I've tried to give you a good basis. The law is the founding for all regulations, because the regulations are the codification of the law. So that's why I started with the law, because it's basic definition that links GMPs and adulteration.

Q. Is it your opinion that every single Valsartan pill manufactured with ZHP's API, after the process change that we discussed earlier today, was adulterated?

MR. VAUGHN: Object to form.

A. Has the potential to be adulterated, yes. Unfortunately ZHP did not -- did not do investigations and understand what was happening. It's my opinion, however, as I state in my report, that the presence of NDMA and NDEA could deem the product adulterated. So therefore, any API or any finished dose product containing those would indeed be adulterated. So the fact that the process changed was the result -- was what resulted in those impurities. It makes all of those potential adulterated product.

Q. Did FDA send any warning letters to ZHP with respect to its CGMP practices regarding the

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manufacture of Valsartan before 2018?

A. You said a warning letter? Is that what you're asking? I don't believe a warning letter on that issued before then, no. But they certainly had -- the company had information before the FDA warning letter came out about this problem.

Q. You testified that you did a hazard assessment in this litigation, correct?

A. That's where I started, with the terms of -- in terms of NDMA and NDEA.

Q. How many hours did the hazard assessment take you?

A. Only five or six hours. I already had knowledge of where to go to look in terms of sources and resources, 'cause again I'm familiar with nitrosamines and NDMA. So it wasn't difficult for me to collect the -- I already had textbooks, for example, that talk about the impurities, those particular compounds, and their risks and their hazards.

I also already had in my possession the tox -- IARC document that I had from I don't know which project several years back, but I had looked at NDMA as an issue, not in a pharmaceutical case, but in other contexts, so five to six hours to go through

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those documents based on the fact that this was something I had looked at before and I was very familiar with what NDMA is, and what NDEA is.

Q. And you conducted a weight-of-the-evidence methodology here, you testified. How long did you spend on that?

MR. VAUGHN: Object to form. Misstates prior testimony.

A. So I told you that, based upon my review of the monographs, the authoritative sources, the text books, I didn't go through every piece -- didn't pull every piece of literature, but I used those as a resource for my evaluation of hazard. So that evaluation of hazard was weighing the information that existed out there and the consistency of the information is incredibly good.

There are no authoritative bodies that say that they are not carcinogens. And no textbooks that say they are not carcinogens, NDMA and NDEA.

Q. I think my question was just how many hours did you spend on your weight-of-the-evidence analysis?

A. That's something I can't give you an exact time. I mean, the entire time I wrote my report, I am weighing evidence based upon what I see,

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what's available, what -- what evidence says on both sides, either answer to my questions -- I don't come in to the evaluation with a decision already made about what my report is going to say, and my report evolves as I review the information.

So weight of the evidence is, all of the information is being weighed in terms of the -- the evaluation of my report.

In regulatory, in the regulatory world, when I am developing my regulatory opinions, the process there is not the same. It's applying the training, experience and understanding of the the regulatory language, the guidance documents, the things that there are, and whether or not what is there is consistent with what the evidence tells you in the case; statements by the company, warning letters, official actions, what the labeling may say, if it's a labeling issue. So that's a little different.

Q. But you aren't able to tell me how much time you spent in your weight-of-the-evidence assessment?

A. I can't give you an exact number, no. It's not like I sit and write down, "This day, we're giving these documents," I applied only a

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weight-of-the-evidence approach to what I was looking at. I'm trying to explain to you that in two different parts of my report, there's different methodologies that you may use. Weight of the evidence is used for typically weighing scientific information to come to some understanding of what that scientific information says about the relationship or the finding.

In this case, that was my five to six hours I spent going through the authoritative documents, looking at whether anything had changed since the last time I looked at it in terms of the cancer hazard, and whether or not NDMA and NDEA were still identified as compounds that increase the risk of cancer in humans, so that's what I told you was five to six hours.

After that, the majority of the time on this case was spent with reviewing evidence in the case, going back to the regulatory language, the guidance documents, and providing that discussion and analysis.

Q. You said the last time you looked at it. When was the last time you looked at NDMA and NDEA?

A. Before this case, probably about four years ago.

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Q. And in what context were you looking at that?

A. The context of an environmental contamination issue.

Q. Can you explain?

A. It's a confidential project for a client. So, no. I can't give you any more than that.

Q. What were you doing for this client, without identifying the client?

A. I was doing a hazard evaluation. The presence of NDMA particularly, in the environment.

Q. And it's for litigation?

A. No, it's a consult project.

Q. Was it a pharmaceutical company?

A. No, it was not a pharmaceutical company, the one I'm thinking about.

Q. Did you find any changes in the science with respect to NDMA and NDEA between then and now?

MR. VAUGHN: Object to form.

A. Not with respect to the cancer hazard, no.

Q. When you were doing that other project, did you quantify any risk with respect to a dose of NMDA?

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A. No, this was another situation where the issue was whether or not there was an -- an overall risk associated with the presence of the contaminant. And I'm going to call it "contaminant" here because this is not a drug product.
Q. If you could turn to paragraphs 11 and 12 of your report.
A. Yes.
Q. Have you ever used these two paragraphs in another expert report?
A. I'm thinking, only because I haven't done that much generic drug work, so I'm thinking. I might have used some of the information in -- in paragraph -- the paragraph that's -- 24 for a project that I worked on for a generic drug, yes, but it was years ago. I haven't done a generic drug case in quite, maybe six, seven years.
Q. I'm sorry, I was asking about paragraphs 11 and 12.
A. I thought you said pages 11 and 12, I'm sorry.
Q. Okay.
A. Okay, we're talking past each other. I have used very similar language to 11 and 12 in other reports, yes, because I am often asked -- I have done

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many cases like this, where I'm asked to serve as a regulatory expert or a toxicologist. And so the methodology that I use is the same, whether it's a consulting project, or a litigation project, for example, with risk assessment.
And then I also am giving in paragraph 12 why it is that risk assessment is a methodology, a weight-of-the-evidence as well, that makes sense to use for answering questions in my area.
Q. So these two paragraphs were cut and pasted from another expert report, correct?
A. I don't know about word for word, but they are very similar, yes, because again, this -- I get asked the kinds of questions I'm addressing here in other cases in the past, yeah.
MS. MILLER: All right, let's go off the record and take a break.
VIDEOGRAPHER: Going off the record, the time is 4:39 p.m. Eastern Time. This is the end of media unit 5.
(Recess taken.)
VIDEOGRAPHER: We're back on the record. The time is 5:02 p.m. Eastern Time. This is the beginning of media unit 6.
(Continued on following page.)

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EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. Dr. Plunkett, have you ever advocated before a public agency on behalf of a company that manufactured a product with genotoxic properties?
MR. VAUGHN: Object to form.
A. In California, is that what you're asking? There's a California pesticide issue I worked on, but I don't know that that compound -- it wasn't NDMA, and it wasn't quite the same kind of compound, but the issue was whether or not there was a threshold for cancer there, based on it acting through non-genotoxic methods. Is that what you're asking me?
Q. I'm just asking you --
A. Well, I did. I worked on a project for a pesticide that was in California -- in California, they ave a -- the California agency that regulates pesticides, outside of BPA, has under Part 65, has a panel you can go before. There was a particular pesticide that was acting -- wasn't a clear genotoxin that was acting through potentially threshold methods, and whether or not there was a cancer risk that should allow the product to have to carry a Part 65 warning, even though the product was marketed

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in the U.S. legally as a pesticide under EPA.
Q. Was that product genotoxic?
A. I'm just telling you now, it's operating through a non-genotoxic mechanism. So there's compounds that we understand, instead of causing direct damage to DNA, may cause changes, for example, in proteins that -- or signaling pathways that control cell proliferation. And some of those compounds at certain high doses, you can identify that the signaling pathways overwhelm the normal machinery of the cell such that you get uncontrolled proliferation, so these are considered non-genotoxic carcinogens.
And so in this case, that's not what we're talking about, we're talking through genotoxins that are acting through direct DNA damage, but not genotoxic carcinogens, can be -- they have risks and how they can be assayed differently based on the mechanism and the mode of action.
Q. Have you ever done consulting work for a company with respect to a product that was genotoxic?
A. At Environ it's possible, yes. There might have been a product that had genotoxicity, an industrial chemical project or -- not in the aspects of the pharmaceuticals, no. Or -- you can assume --

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even a consumer product other than a pesticide now, that I can think of.
Q. Have you ever advised a company to stop manufacturing a product because you thought it was genotoxic?
A. I wouldn't have done it based upon just genotoxic. We did advise companies, I had, when I worked at Environ in particular, we advised companies about cancer hazards for different kinds of products and we would give them the advice that the product had a hazard that either needed to be considered or would affect the regulation of the product.
But I can't think of one where I gave advice just on genotoxicity because typically, for products, you look beyond that and you look for a genotoxic data backed up by animal data or some other in vivo data, which is why this product, with these products it's so important, because you have the whole picture, you have the -- you have the in vivo data to show that indeed, you can get beyond genotoxicity to actual cancer.
Q. Is it your opinion that every genotoxic -- every product that contains genotoxins should be removed from the market?
A. I don't think I've formed that opinion,

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no. Because it's very case-specific and exposure-specific, and exposure-potential-specific.
But certainly, there are cases of human drug products, either prescription or over-the-counter, the presence of genotoxicity as a hazard is acceptable for things like cancer drugs, because of the issue of the benefits so outweigh the risk. Many cancer drugs actually have potential to initiate cancer later in life if you're on them long enough. But generally, no. That would not be the case for drugs or products you would want those drugs or products to be not probable carcinogens, for example.
Q. Dr. Plunkett, are you familiar with the chemistry behind the TEA process and how that led to the formation of NDEA?
A. Only from some documents I've seen describe it but again, that was beyond the scope of my work. It was my understanding that the chemists in the case would be handling the details on the process and the -- and the steps in the process that were readily identifying as posing a risk.
Q. Can you explain for dummies how the NDEA was formed?
MR. VAUGHN: Object to form.
A. So I have in my report the explanation

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for dummies so let me go there, where I describe the two processes. Let me find it.
On paragraph -- long paragraph, I apologize for that -- starts on page 16, paragraph 28. And I go through the understanding and the explanation about the -- about the TEA and the process, and this actually deals with, in 2019 what ZHP found with respect to the cause, and it -- and I don't want to go into the detail, but essentially I think those things are described there.
Do you want me to read to the record or just refer you to that paragraph? Because it talks about the TEA process, it also talks about, I believe, the zinc chloride process as well.
Q. I'm sorry, what page are you on? I don't see what you're referring to.
A. Paragraph 28, the easiest way for me to send you there. It starts on page 16, it goes over -- I apologize, this is like a very unusual paragraph for me. It goes on for two-and-a-half pages, over to page 18.
Q. Can you just point me to where it describing how the NDEA was formed?
A. So for the TEA, it comes on the second -- the third page, 18. And it starts to the

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the top of the page, "N-Nitrosodiethylamine is potential process-related impurity which has a similar formulation mechanism as NDMA. It is most likely generated in terminated TEA process with" -- this is -- it's an acronym, "NaNO2," which is sodium nitrate, "quenching, in which TEA-HCl (containing potential impurity of diethylamine) and nitrous acid, exist simultaneously to render the nitrosation reaction to proceed."
Want to keep reading? I mean, this is the paragraph I'm talking about.
Q. What is this quoting from?
A. Quoting from, starting back on page 17, starts within 2019, this was ZHP's statements regarding their investigation. So I'm referring to a ZHP document, pointing to pages 932 to 933, last page Bates.
Q. Is it your opinion that it was known in 20123 that TEA could transform into diethyline under conditions similar to those involved in the manufacturing of Valsartan API, and that that could then react to sodium nitrate and hydrochloric acid in the quenching step to create NDEA?
A. I don't think I ever formed the opinion that all those specifics were taught in the

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scientific literature. Instead, if you look at my opinion or statements in my report about 2012, it's teaching that N-nitrosamines, generally, are potential products that can be produced during the different processes. Again, for details on this, Dr. Hecht, the chemist, has many pages in his report where he discusses the -- these issues about the chemical reactions and the foreseeability.

Q. As I recall, the literature you cited was about the degradation of DMF. Did you cite any literature identifying that TEA could transform into diethyline that could react with sodium nitrate and hydrochloric acid and that could lead to NDEA?

MR. VAUGHN: Objection to form.

A. I think I -- I don't believe -- I don't believe I've cited in my report a specific document that gives all those details. However, and that's why I then pointed you to, first to Dr. Hecht, who gives a very detailed description of it, and then also the two sources of information that -- excuse me -- were brought out in depositions.

Q. Were those two sources of information related to DMF and NDMA? I'm asking about the TEA process. Have you cited any literature that you believe shows the foreseeability of NDEA developing

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as part of the TEA quenching process?

MR. VAUGHN: Object to form. Argumentative.

A. So I would point you to the report of Dr. Hecht, discusses the foreseeability issue with these particular -- these particular processes. Again, it -- that was not -- scope of my work did not include doing what Dr. Hecht did.

Q. Are you familiar with M7?

MR. VAUGHN: Object to form.

A. As far as if -- by M7 you're talking about the amendment to the ICH, is that what you're talking about?

Q. "M7, Assessment and Control of DNA Reactive Mutagenic Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk, Guidance For Industry," are you familiar with that document?

A. Yes, that's what I was referring to, because it's tied to the ICH.

Q. It's about a hundred-page document, does that sound about right?

A. I have no idea how many pages it is.

Q. Does the top of every single page say, "Contains non-binding recommendations"?

A. I'd have to look, I don't know. Again,

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it is a guidance document so it doesn't surprise me if it does, but as -- I think I covered this earlier in the day with you in some detail. How, what guidance means, and in my experience, what guidance means to the industry that I have worked for.

Q. I think you said earlier, I believe you said earlier today that there's language in the introduction to these documents about them being only guidance, but I don't believe you testified that every single page has a header that says, "Containing non-binding recommendations."

A. I don't think you asked that question. So you know, I don't know if every single page does, it's possible that they do, but regardless of whether they are labeled on the document as nonbinding, they are still very important documents in terms of what industry should be considering and using in terms of guidance as they develop their processes to ensure that they have full compliance in terms of GMPs, but have a adequate quality system as well for their drugs.

Q. Just the term "nonbinding."

A. I think you asked me that before and I think -- I think we agreed to the word "recommendation," but I told you also that in my

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experience, with guidance and similar documents like the M7, that those indeed are guidance or recommendations that industry implements in order to comply with certain parts of their -- of the FDA regulations or the need for produce a quality product.

Q. You refer in your report to "ICH core principles." Do you recall using that term?

A. I may have. I don't know. Possible I did.

Q. Is there a document or literature that lists what the ICH core principles are?

A. If I used the word, I should have had a citation for it, so I need to look. Where are you looking in my report?

Q. Well, you use it multiple times, but if you look it -- at the top of page 31 you say, "ICH core principles." And I just -- I just want to know --

MR. VAUGHN: Dr. Plunkett, take your time to read the entire paragraph from your expert report, starting on the page before.

MS. MILLER: I was not suggesting she not do that, Brett.

MR. VAUGHN: I didn't say that you

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suggested it, I was just --
MS. MILLER: Okay. She asked me where she used the --
MR. VAUGHN: You saw on the page before, and tell her the next one. I'm telling her to read the whole paragraph.
A. So core principles would relate to the specific steps or criteria that are set out in the ICH guidelines, and that is indeed how I described them, bottom of page 30, I say -- I actually have the opinion that what Dr. Gu testified to, and I say, "Failed to apply core principles of the ICH guidelines related to identification of impurities."
So for example, in the ICH guidelines, there's different things that are described in terms of quality, and one of them has to do with identification of impurities. There's other core principles that are also described and I'd have to pull the guidance documents out in order to list them all for you.
Q. Do ICH documents have a section called "Core Principles"?
A. I don't know. I don't recall. I'd have to go look.
Q. How do I know in reading an ICH document

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what you mean when you say "core principles"?
A. The things that -- what they outline as being important to compliance for quality. So they have certain things that they describe. The easiest way would be to pull the document up, if you want to do that. And you can see different sections or different discussion points. And impurities, identification of impurities in -- is one of those "core principles."
I'm using the word "core principle" based upon my experience with, you know, referring to those. In terms of describing what they are. It's just like the regulations, the 21 CFR Section 210 and 211, set out the core principles for CGMP, one for finished dose manufacturers on 211, and general principles or core principles also within Section 210. I'm not giving it any -- I'm not meaning to give it any special magical meaning, if that's what you're asking me.
Q. Is the term "core principle" ever used by ICH or by the FDA?
A. I have no idea. It's something that in the industry, and in my experience, I've heard people use many times. I've heard FDA people give lectures talking about the core principles of GMPs, core

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principles of labeling regulations. I mean, there's -- I think it's a common term used when you're talking about compliance and regulations.
Q. Can you identify someone whom you've heard use that term?
A. My business partner, Dr. Rudenko, who used to work for FDA, one of my other contractors in my business, Dr. Merker, who used to work at CFSAN.
Q. I thought you said FDA speeches. That's --
A. Well, she's -- she's given slide talks and presentations and I've seen her -- Larissa and I had a business relationship off and I since 1989. We've worked together three times. She went to FDA for 15 years, and while she was there, I used to hear her talks, go to her seminars, I've heard her do that.
Dr. Merker recently retired. He still uses FDA lingo all the time. He talked about core principles of food safety assessment.
So again, I think this is kind of an odd -- an odd argument we're having if it's an argument. I mean, to me, core principles has a special English language meaning. It's things that

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are inherent to the system, be it a regulatory system that controls food safety, the regulatory system that controls all the drugs that must be adhered to.
Q. When you talk about ICH core principles at the top of page 31, you mention, you write, "(e.g. ICH Q3A)".
ICH Q3A provides guidance about impurities in new drug substances, correct?
A. I'd have to pull it up, but I think it does.
Q. Does ICH Q3A apply to changes in already -- to manufacturing changes to existing API products?
MR. VAUGHN: Object to form.
A. I would say that it does but I would neat to look to see if they exclude that. I don't recall that being excluded in the discussions of these types of principles. Regardless of whether you're making a change to an existing ANDA, it's a new process for making the drug. So certainly, those same principles or recommendations or guidelines would apply.
Q. Are you familiar with any literature that you can cite to me saying that ICH Q3A would apply to manufacturing changes to existing API?

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MR. VAUGHN: Object to form.
A. I haven't look for that, so I can't answer that. I'd have to look, but also that question that I raised as I was doing my -- writing my report.
Q. When did the FDA adopt ICH M7 as guidance?
MR. VAUGHN: Objection, foundation.
A. I believe it was in my report. I'm going to say 2016, but it was put forth publicly in 2014.
Q. Was ICH M7 adopted by the FDA before or after process changes at issue here?
MR. VAUGHN: Objection, form.
A. So I believe at least with one of the process changes it would have been after, but it doesn't matter because the M7 recommendations or guidelines or statements are essentially consistent with the 1999 ANDA guidance document by FDA -- that FDA put out when it talks about considering the issue of potent toxicants, or toxic compounds.
Those are always part of the -- of the -- of the equation and impurities have been recognized as a potential issue to be addressed for compound -- for drug products for a very long time.

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The language is a bit different, but that doesn't mean that there was no recognition of the need to know the potency or the toxicity of potential impurities.
Q. You write in your report that ZHP's change to utilizing chloride and dimethylformamide was internally classified as a critical change, is that correct, do you recall that?
A. There is a paragraph where I quote from either a document or a deposition, yes. And I -- if you show me where you are, and then I'll clear it somewhere else, but I do know that, yes.
Q. Does the FDA use the term "critical change"?
MR. VAUGHN: Object to form.
A. In terms of their guidance on when to submit a supplement, is that what you're asking me? They use different language.
Q. What languages does FDA use?
A. It uses, the issues would be major versus minor, minor versus major changes. But regardless of that, FDA's warning letter points this out, I think that's where there discussion is, if the NDMA themselves points out to the company that you said something was minor, you said something was

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minor in your DMF or in your submissions to us, but yet you called it critical. Based on that, it's an important concern as well, the FDA, did.
Q. Do you know what ZHP meant when it said "critical"?
MR. VAUGHN: Object to form.
A. I have no information to indicate that they meant anything other than important. "Critical" usually means important.
Q. Do you have any reason to believe that ZHP's internal use of the word "critical" was intended to mean major under the FDA's --
MR. VAUGHN: Object to form.
A. If it's meant to mean major, to me, the important thing was not exactly how they classified it, even though FDA points to that issue. The issue for me is they made changes, didn't do a full assessment on the impact of those changes, even though those things indeed had important implications for the impurity profile of the drug.
Again, this issue of major-minor critical changes, other experts in the litigation have a lot more to say about it than I do. I point to it mainly because of my opinions related to the fact that the product, FDA was recognizing that the

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company had serious concerns with GMPs and product quality. And one of the reasons -- one of the things I cite to was the fact that the company didn't share with FDA their exact descriptions of those process changes when they -- when they made them to the DMF.
Q. Which description of the process change did ZHP not share with FDA?
A. They didn't call it a critical change which would -- which were a different implication than a minor change.
Q. But we just agreed that "critical change" is not an FDA terminology, right?
MR. VAUGHN: Object to form.
A. But "minor change" is. And if the company is distinguishing critical versus minor, which, if you read the deposition testimony, they indeed are, and then if you look at the FDA letter to the company, they indeed see that as an issue within the company as well.
I'm just saying that, to me, that's evidence to show that FDA is recognizing that that was a consideration in terms of their decisions regarding the warning letter they issued and their decisions or their judgments regarding the lack of GMP compliance.

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Q. I may have misunderstood your testimony but I thought you testified that they didn't provide the FDA with a complete description of the process change.

Do you have reason to believe that ZHP failed to provide the FDA with a full description of what the process change was? Object to form?

A. That's not what I said. I said that they didn't use the same language in their description with FDA. They called it a minor change, not a major change or a critical change, which is the language they are using internally.

Q. Are there any internal --

A. So --

Q. -- are there any internal communications where ZHP uses the term "major change"?

A. To FDA, ever? I didn't --

Q. I said internal. I said are there any internal documents where ZHP has referred to this changes as a major change?

MR. VAUGHN: Object to form.

A. I didn't look for that, so I can't answer that. I don't know. I think my mention of this has to do -- that this issue in my report has to do strictly with the discussion of the FDA findings

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in the warning letter. The FDA themselves talks about it. Other than, I do talk about the background on what types of, how you classify certain changes and whether you have to put in a pre-amendment supplement, or whether you can put this in as a CBE, or whether you can simply submit it as part of an annual report.

Q. Do you compare ZHP's definition of "critical change" with the FDA's definition of "major change"?

A. Well, I lay that out on my report, no. Again, that's something -- I've seen reports where other experts in the litigation are doing some of that.

Q. Do you know whether ZHP's internal definition of "critical change" is the same as the FDA's definition of major change?

MR. VAUGHN: Object to form.

A. I can't answer that without looking. I don't know. I discuss this so if you need to see what I said, I discuss this on pages -- in paragraph 27, paragraphs 14, 15, and then I talk about the comment from FDA at paragraph -- right before paragraph 28 on page 16. Rather a long paragraph, I apologize.

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Q. Do you know what MSP is alleging in this case?

MR. VAUGHN: Object to form.

A. No, I don't know what MSP -- I already told you, you asked me questions and I haven't seen the complaint, so if I haven't seen the complaint I can't answer that. I guess maybe what I should tell you to add to this answer, though, is that, I am aware that the cases I'm working on, that there -- that the Plaintiffs are alleging injuries of cancer or fear of cancer related to their exposure to Valsartan drug products. That I am aware of. But I don't know what's in -- it's in the MSP complaint, where that's even the same complaint, I can't answer that.

Q. Were you retained for one specific case or were you retained in the Valsartan litigation generally?

A. I'd have to look at my confidentiality agreement. I don't have a retainer or a contract. I, right now I'm aware of a case, a Valsartan case, that's this particular case that I'm working on, and the issues that I'm addressing have to do with, it's my understanding there are more than one Valsartan case. But dealing with the toxicology, the hazard,

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the increased risk and then -- as I say in any report, the general regulatory overview responsibilities of a manufacturer and then my analysis of what the evidence in the case says as it relates to the regulatory requirements of a generic drug company making either an API or a finished dose.

MS. MILLER: I think I'm close to the end of my questioning. I need a break to confirm that. So let's take five to ten minutes. Lee, could you tell me how much time --

VIDEOGRAPHER: Could we go off the record, counsel? Going off the record. The time is 5:36 p.m.

(Recess taken.)

VIDEOGRAPHER: We are back on the record. The time is 6:02 p.m.

MR. VAUGHN: Real quick, I just want the record to reflect that we've had multiple breaks on our own, and now we've been back for over ten minutes waiting for it to start. Go ahead, Jessica.

EXAMINATION (Cont'd.)

BY MS. MILLER:

Q. Dr. Plunkett, you used to have a company called Integrative BioStrategies, correct?

A. Yes.

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Q. What happened to that company?
A. When I took on my new business partner in January of 2020, in June of 2020, we decided to form a partnership and change the structure of the company so we were equal partners. So the ID was a company where I am -- I was the owner and my husband was an employee and Larissa originally, Larissa was working as an employee, but she and I are equal in terms of our business development.
So we -- we formed a new company and, by doing that, we gave it a new name because we also started to have some new focuses to our business.
Q. Does the new company have different employees from the old company?
A. Yes.
Q. Who has left and who has joined?
A. So it's joining, so myself, I'm an employee, my husband is an employee still, he's still our -- administrative assistant, business manager; Larissa and I are joint partners in the company, fifty-fifty now, and her husband, who is also a Ph.D. physiology biochemist and also an employee of the company.
Q. Were Larissa and her husband evolved in Integrative BioStrategies?

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A. Her husband no. Her husband is new, he's only been around about two years. Initially, if you've ever read my depositions, in 2001, I joined Larissa, who was the original owner of Integrative Biostrategies, so she and I worked together from '01 to '03. She left, went to FDA, and then I became the sole owner when she left.
Q. The only new person that you haven't worked with before is her husband?
A. Yes, that's correct.
Q. And what's his name?
A. His name is Austin Mirchelof.
Q. Merchant, like the Merchant of Venice?
A. No, M-i-r-c-h-e-l-o-f. He's a -- oh, gosh what's his background? It's like some kind of an Eastern European name, and I forget, I apologize, I've forgotten what it is.
Q. And where is BioPolicy Solutions based, do you have an office?
A. We have two offices, one in Houston, Texas here for me. We chose to have -- especially when we started the company in two 2020, it was advantageous. Her office is located in Ventura, California. We both have home-based offices. This company is incorporated in Texas because the -- the laws are more favorable to businesses here than they are in California.

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Q. Are you currently in your office?
A. Yes.
Q. And is your office in your home?
A. Yes, it is.
Q. When you --
A. And hers is also in her home.
Q. What's more favorable about Texas over California?
MR. VAUGHN: Object to form.
A. Taxes, regulation, and all the things you have to do in terms of businesses. That was the advice of our accountant, to incorporate in Texas instead of California.
Q. Do you have a Twitter account?
A. No. I do not like Twitter.
Q. Has FDA ever asked you for your views on nitrosamines?
A. No, not in the context of these issues. And I don't believe I've ever had a conversation where they have asked for it even, or ever over the years where I have worked in projects where FDA and I have interacted.
Q. What percentage of your income last year

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came from litigation?
A. Last year, about fifteen percent of my income. My -- our new company has had a real focus on regulatory, strategic planning, due diligence, and regulatory problem-solving for emerging companies using emerging technology.
And during COVID, obviously, litigation slowed down a whole lot. Many of the cases I'm working on or have worked on are still pending, there's been a promise of trial for the last three years, nothing has happened. So...
Q. How many hours would you say you spent in 2020 on litigation?
A. I don't know. I'd have to go back and look at my records. I don't know. In 2020, it was very few.
Q. I'm sorry, did I say 2020? I meant '22. But in 2022, 15 percent of your income was from litigation?
A. Yes. About -- and it was actually about 15 percent of my time because, unlike the old company, our rates for projects are the same regardless of whether it's a regulatory project or a litigation project. It's all charged at $400 an hour.

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Q. So can you estimate for me about how much money you made from litigation last year?
A. I haven't done my taxes yet, so no, I can't do that. Ask me in a couple of months, and I maybe can tell.
Q. You said it was 15 percent. Don't yet know about how much you earned last year?
A. Well, my personal income, and then there is the income for the company, are you talking about my personal income?
Q. Yes.
A. That 15 percent may not apply. I can tell you much I make a year, I draw $170,000 a year salary. But the 15 percent number I'm giving you would be the business billables overall in that practice area, and some of that may have been Larissa and some me.
Q. When you say you draw $170,000, do you also draw profits?
A. I can at the end of the year if there's any money not distributed. We have more overhead now because both Austin -- Dr. Mirchelof and my husband are non-revenue-generating employees. They assist on projects and we may charge Austin's time out, but it's at a much lower rate.

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Q. Do you know how much you personally earned from -- do you know how much you personally billed plaintiffs' lawyers for litigation in 2022?
MR. VAUGHN: Object to form.
A. I can't answer that, because it's too early. Again, if you ask me that question in -- after the tax season, I might be able to tell you.
Q. Do you know approximately how many different cases you worked on in 2022?
A. You have my trial list. That tells you how many depositions that I've been involved in. And as far as cases, I'd have to look at my trial list to see whether is it or isn't there. I mean, I have maybe four active litigation areas. And then I have two or three that are dormant. That I don't know what's going to happen. But the top litigation is in Bankruptcy Court, so who knows if that's going to come back --
Q. I'm a lawyer.
A. Okay, there you go. I have -- I've still -- I still believe there's unresolved cases in the IVC filter litigation, but I haven't been approached with anything new in that in the last eight to -- I would say the last year, actually.
Q. When you say you have four active

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litigations, what are those?
MR. VAUGHN: Object to form.
Dr. Plunkett, slow down just a little bit so I can get the objections out.
THE WITNESS: I'm sorry.
MR. VAUGHN: Okay.
A. Active litigations would be this, this litigation area, I'm active in the -- Valsartan, what the other, oh, Taxotere, but theres' not a lot going on there. I am getting ready for the Preservation deposition, that litigation, some time in the spring. I'm working in the -- one of the Ethicon Mesh cases --
MR. VAUGHN: I'm going to caution you to not disclose any confidential information, Dr. Plunkett.
A. Okay, all right. The other two things I'm working on, I have not produced reports in yet, so I guess that would be something I should wait until I have produced a report. I assume that I will be, you know, those will come to fruition but right now, as far as active depositions or trials would be Taxotere, and then this deposition here.
Q. So the other two are things that you have not been disclosed as an expert yet?

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MR. VAUGHN: Object to form.
A. That's correct -- I'm sorry, that's correct. Well, as far as I know, because the reports haven't been -- I'm working on reports, but they have not been completed.
Q. Who contacted you to request that you serve as an expert in this litigation?
A. I don't know whether I first heard from Mr. Vaughn or first heard from Mr. Nigh, both of whom I, you know, encountered before.
Q. Where did you encounter Mr. Vaughn before?
A. In a medical device litigation. It sounds like maybe I shouldn't say.
MR. VAUGHN: You can answer which medical device litigation, just don't comment on the status of the litigation, please.
A. Oh, okay. In the hernia mesh litigation, and then in the -- Mr. Nigh -- he and I have crossed paths but I'm trying to think, I can't think of the exact -- he's not been presenting attorney with me, but he's been involved in different cases I've worked on and I'd have to go back and look at see where Levin Papantonio, the firm he was with, was listed. It's possible that there was -- he was

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listed in the talc litigation with me but I'm not sure.
Q. Have you worked with Mr. Slater before?
MR. VAUGHN: Doctor, real quick, I also want to caution you, do not disclose any litigations in which you have not yet disclosed an expert report.
MS. MILLER: She said she wasn't going to --
MR. VAUGHN: I'm sorry, she was going kind of quick. I must have missed it.
Q. Have you come across Mr. Slater before?
A. In this litigation, I have.
Q. Is this the first litigation in which you worked with Mr. Slater?
A. That I can recall.
THE WITNESS: And Mr. Slater, apologize ahead of time if there've been other interactions.
Q. Nobody forgets Mr. Slater. Do you have any other litigations you're working on with Mr. Vaughn, other than medical device, hernia mesh, and this one?
A. No, I don't believe so.
Q. Okay. You testified that only 15 percent of the revenues, I think, of BioPolicy

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Solutions come from Plaintiffs' lawyers. What kinds of clients constitute that other 85 percent?
MR. VAUGHN: Object to form.
A. Currently, in 2022, and 2021 as well, a majority of them were either -- are either companies that manufacture or make products or ingredients for either the food industry, pharmaceutical industry, or industrial industry as well as, because we work with some enzyme manufacturers, and then we -- we also work with -- do due diligence with investors at times for review of technologies in the space of emerging technologies, new ways to manufacture products that haven't been implemented before.
And then the other work is, I still do some patent work, putting together, doing patentability evaluations, and strategy for taking an invention for market with university-based inventors.
Q. Some invoices we saw, you've billed about 150 hours since litigation, does that sound right to you?
MR. VAUGHN: Object to form.
A. All in all, and throughout the work, it's possible. I don't know, I didn't count it up. I apologize. I probably should have done that but I didn't.

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Q. Do you have additional unbilled time?
A. Just for this time in January getting ready for the deposition. So no additional time on reports. Obviously, you have my report, and this time at deposition.
Q. How much time did you spend getting ready for the deposition?
A. It's a guess, I haven't added it up for January, I haven't done my billing, so I would say another twelve, 15 hours, maybe. Twelve hours.
Q. And how much of that time was spent with Plaintiff's counsel?
A. Probably half the time with Plaintiff's counsel, and the other half on my own getting ready.
Q. Over the course of writing the report, did you request additional documents from Plaintiff's counsel that you hadn't received previously?
A. I requested additional documents when I saw, for example, in deposition testimony, certain area that I asked if there were additional documents that might relate to that, yes.
I asked for, at one point, right towards the end of the time I was preparing my report, I asked if any of the other experts in the case for Plaintiffs had reports ready. First Dr. Hecht did.

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I did see Dr. Bain's report, and Dr. Russ' report as well, but those were all right before my report was due. And then I -- I did ask them after I submit my report, but I would obviously assume I would like to see defense expert reports that overlapped my area if they were in before my depo, and I was lucky enough that a few of them were.
Unfortunately for me, they came in right before Christmas, so it wasn't a whole lot of fun working on them over Christmas, but I did review the ones provided.
Q. Did you review drafts of the Bain or Hecht reports before they were finalized and served?
A. No. I asked for final reports. I can't tell you that I didn't see them at the same time they were being served, the same day, but or -- but I certainly saw what I consider final reports.
Q. Were they signed when you saw them?
A. Yes, they were.
Q. Are you relying on Dr. Bain -- I don't know if she's a doctor. Are you relying on the Bain or Hecht report ares in your opinions?
MR. VAUGHN: Object to form.
A. So I cite to Dr. Hecht as part of the evidence for "foreseeability." I defer to him. But

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I'm not relying on him for any of the opinions related to responsibility of the manufacturers or the other general opinions in the regulatory area.

I also am not relying on him in terms of my increased risk opinions, either. Those are independent of, actually all of the other experts that I've seen. I'm not relying on Dr. Bain, although I have seen her report. And I did -- I think I said to you a couple of times during the deposition today that that's why I mentioned her. Some of the questions you asked me are things that I know are covered in those other expert reports. And they were beyond the scope of some of the things that I developed or was asked to do.

Q. Do you have an opinion as to whether Dr. Hecht is more credible than ZHP's chemistry expert, Dr. Xue?

MR. VAUGHN: Object to form.

A. I haven't formed an opinion comparing them head to head in that way, no, I believe Dr. Hecht, based on having seen his, I guess his CV or resume that was attached to his report, and having read his report, he certainly appears to be a credible, competent, well-trained chemist. That's all I can say. I mean, I don't try to compare the

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quality of one expert versus the other.

Q. You have similar opinions with respect to Dr. Xue?

MR. VAUGHN: Object to form.

Q. Have you read his CV report?

MR. VAUGHN: Object to form.

A. Can you spell that name that you gave me?

Q. X-u-e. You said you had read his report. We talked about it earlier.

A. A Defendants' expert or a ZHP witness?

Q. He's a chemist and you said earlier that you had read his report. He's an organic chemistry professor at the University of Maryland.

A. Oh, as -- that's what I'm asking you, as an expert report? Is that what you're asking me? Yes, I did. That's on my list of ones I had reviewed.

Q. Correct. You testified that based on Dr. Hecht's report and CV, you thought that he was a credible chemist and I'm asking, did you reach the same impression with respect to Dr. Xue?

MR. VAUGHN: Object to form.

A. Certainly, Dr. Xue has chemistry credentials. I don't know what else to say, I mean,

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it's -- again, I don't -- I don't -- I did not consider his report when I developed my report, and since I defer to Dr. Hecht, I paid a little more attention to looking across his credentials and what he was saying.

Q. You testified earlier that you have represented companies before the FDA, is that correct?

A. Yes, I've worked as a consultant to companies and we've had meetings or I've helped them respond to regulatory issues to the FDA. With the FDA, yes.

Q. So on behalf of those companies, you've had meetings with the FDA?

A. Yes.

Q. When was the last time you had a meeting with the FDA?

A. Two months ago.

Q. And what was that with regard to?

A. It was with regard to safety assessment for a new type of food produced by novel methods. That's all I can say.

Q. Were you at the FDA for that meeting?

A. No, they were still doing virtual meetings. I haven't -- I don't believe FDA has

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resumed in-person meetings for normal interactions yet. At least that was my understanding based upon the last meeting we had.

Q. Have you had meetings at the FDA prior to COVID?

A. Yes, I have.

Q. When was the last meeting you had at the FDA itself?

A. It was not -- not over the phone. I'd have to go back and look, I don't know.

Q. Which FDA office would that have been in?

A. That one would have been -- oh, I know which one it was, it was -- actually, the most recent, I keep forgetting about this, the most recent one would have been a meeting that FDA convened in 2020, right before the shutdown, on talc at the FDA headquarters. That was the last in-person meeting I went to. Before that, I'd have to go back and look, it would have been probably six or seven years before that easily.

Q. Were you invited by the FDA to that meeting or was it open to the public generally?

MR. VAUGHN: Object to form.

A. It was a public meeting but you had to

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request an opportunity to speak, which I did. And I was accepted as a speaker at the meeting.
Q. And what did you speak about?
A. I spoke about the risks posed by talc particles and specifically issues related to elongated mineral particles, and the need to understand, as FDA at this meeting was trying to do, more about the toxicity of those particles as they related to the difference between different chemical makeups.
So the issue is, the issue FDA was trying to address was, the chemistry may be different in terms of, say, fibrous talc versus asbestos fibers, but both fibers, depending on their shape and their physical form, pose a health risk.
Q. Has FDA ever invited you to speak on a panel?
A. No, not without being introduced through a client, no. Well, it was not -- when I've gone to speak to FDA, it's been being invited by the client to come and talk to the agency about an issue or a concern.
Q. Do you have a template document you use to create litigation reports?
A. Not a template, per se. I have certain

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parts of my expert reports that may look very similar from report to report, because, say for example if you look at the first few pages where I lay out my training and experience, I update that as I need to, but that would be very similar across different reports I prepare.
Q. And so do you have one main document from which you cut and paste, or do you just cut and paste that from your most recent litigation report?
MR. VAUGHN: Object to form.
A. I've done different things depending upon the report that I'm dealing with, so not all my reports are set out with the same format. There are cases I work on where an attorney may ask me to use a format differently than I typically would. So for example, I don't always have a summary of opinions section or I don't always have large chapters, but I break my report up into opinion statements and go through them that way.
So it's been different formats depending upon the need of the case or the desires of the client I'm working with, or my desire to teach a topic in a certain way.
And I usually start, that's the one thing I usually do, I usually start my reports out,

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my background, what I was asked to do, and then I teach first, "Here's basic information," and then sometimes opinions are broken there, and sometimes they are set apart towards the end.
Q. You talked earlier today about paragraphs 11 and 12. Do you remember what document you cut and pasted those from?
MR. VAUGHN: Object to form.
A. I didn't necessarily cut and paste them. Those are two paragraphs that I've had for a long time. I can't tell you when they would have last been used before I put them into this report. I'm trying to think what the last report before that would have been, and I don't know. I'd have to go back and look.
Q. When you say you cut and paste them, do you type them in from scratch or did you copy them from another document?
MR. VAUGHN: Object to form.
A. Part of them are copied in, and then they are often rewritten a bit or edited a bit, depending on whether I'm doing a drug case or a device case, for example, or doing a cosmetic case, or doing -- they could be even different if I'm working on an environmental issue, so -- but those

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basic parts, 11 and 12, where I lay out methodology or descriptions, that's something that I would expect to see in an expert's report. And I -- and so as a result, I typically include them.
Q. I understand. I'm just asking where you copied it from.
MR. VAUGHN: Object to form, argumentative.
A. I told you, I don't know. Because I don't know what the last time I -- it's possible it was the last time I had written a report before this report or it may not be then. I don't know. I can't tell you that off the top of my head.
Each report I write is a living document, so I don't do multiple drafts. I have a draft, it becomes a final report over the evolution of the document and I take notes when I'm writing, when I'm reading a document and that that evolves into a written paragraph.
Q. Do you know whether Mr. Vaughn has ever referred you to other Plaintiffs' lawyers?
A. I have not asked him that. I don't know. I assume he may have. I don't know.
Q. Do you often get referrals from one Plaintiff's lawyer to another?

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A. Well, I often do. And that's because I'm very selective over the attorneys that I work with. I don't take all the cases that come to me. And I typically will not work for attorneys that I don't know. So if it's a reference, that gives me some comfort if the person who is referring is somebody that I trust. It's really important to me that I worked with attorneys that respect me, but also they are going to respect my standards and the way that I believe the work needs to be done.

Q. Okay. I'm going to mark Exhibit 10.

EXH (Plunkett Exhibit 10, invoice dated December 2022 on BioPolicy Solutions letterhead, addressed to Pendley, Baudin & Coffin, marked for identification, as of this date.)

MS. MILLER: What page is that? I'll just -- we are just running short on time.

We're going to introduce as Exhibit 10 your invoices. Alex, are they on one document?

A VOICE: Yes.

MS. MILLER: Okay. I think all your invoices are on one document that Alex is going to put in the share drive that Adam doesn't like, so we can also put them up on the screen.

Q. Do you recall when you submitted your report in this case?

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A. October 31st, I believe, 2022.

Q. Do you know why your December invoice says, "Review of documents and report preparation"?

A. No. It shouldn't. That's a mistake. Certainly, I was reviewing documents and that should be deposition preparation.

Q. So did you begin --

MR. VAUGHN: Are you still putting this up into the share file? I'm not able to access this one yet. Can -- I need to have a document if I'm going to defend.

MS. MILLER: I know but I'm not talking about the document just yet. I'm just asking general questions.

Q. Were you preparing for your deposition in December?

A. Yes, I started preparation for my deposition in December because the date was set in December, I believe. I don't know which day it was set, but certainly there were -- so for example, also when I say review of documents here, part of this time in 27th, 28th and 29th, that would have been reviewing of defense expert reports as well, because that's the time period where I had those in my possession. I don't know that the 19th, that's possible, that I had some defense expert reports then. I don't recall what date those were sent over.

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Q. So that's just an error, you're saying, the part that says "report preparation."

MR. VAUGHN: Object to form.

A. Yes. Because my report was filed the date of it, I believe, I can check again but I'm pretty sure it's October 31st, yes. I haven't -- I have not produced -- if you're asking me have I prepared an additional report, no, I've not.

Q. Okay. We also have this invoice that just says six hundred dollars with no itemization, do you know what it's for?

A. It's for time that I spent working on the project. I don't know.

Q. Was that sent --

MR. VAUGHN: I'm sorry, could I hear that question?

Q. Was that for the MSP matter?

A. I have to go back and look at -- I have to go look for additional detail. If this is what it says, this is, I believe this may have been an invoice that was lost in the shuffle. What was the invoice before this one, can you show me? 'Cause I don't have this file. The invoice before was August of 2022.

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Q. No, this was 2021, right. Is this an early invoice from 2021? This is the only invoice we got from 2021?

A. You got every invoice that I have sent in litigation, so this would have been additional -- this would have been additional work having conversations with attorneys at the start of my engagement. So it's -- this would have been, I would assume the time when I would have been first provided and agreed to be engaged in the project, so probably phone calls. But -- which would have been maybe -- I don't know whether it was an hour -- just a second, let me check something for you.

(A pause in the proceedings.)

Q. Just to make sure I understand, from February 2021 'till May 2022, you didn't do anything in this case?

A. Nothing that I charged for, that's correct. You have everything that I charged for. And I was awaiting some materials, I do know that. But that's all I can tell you.

Q. Stanley Baudin?

A. He is at the law firm -- PBC law, and I

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was told that was -- PBC law firm, again, I don't know the -- Mr. Baudin, I don't know the -- what the initials stand for, but this is where I was told to send billing.

Q. Have you worked with him before?

A. I've been on a phone call where he's been on before, but my principle contacts in the litigation were Mr. Vaughn and Mr. Nigh, and then Mr. Slater was on some of the phone calls as well.

Q. Have you worked with Mr. Vaughn in prior litigation?

A. I don't believe -- well, I don't recall the name from prior litigation, no. And again, Mr. Vaughn is on the phone, I apologize if I'm misremembering.

Q. Do you remember applying to serve on a hydraulic fracture advisory panel in 2012?

MR. VAUGHN: Object to form.

A. No, not a hydraulic fracturing advisory panel, no. I don't recall that.

Q. Do you recall giving a presentation on September 23rd, 2022 entitled "Expert Witness Testimony and Ethics, Science Over Advocacy"?

A. In September?

Q. Um-hum.

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A. Oh, yes, yes, yes, I'm sorry. I am so sorry, it's getting late. Yes, I participated in a webinar that was put on by the Society of Toxicology, a special section called Ethical, Legal -- "Ethical Legal Societal Issues," and it's a special section that brings together people with interest in science ethics, also in legal issues, and also in issues related to societal change that are potentially impacted by the regulations that are developed for different kinds of products that have toxic effects. So --

Q. Were there any attorneys at this presentation, at that webinar?

MR. VAUGHN: Objects to form.

A. Well, I do not know. It was an SOT. It was an internal seminar for the Society of Toxicology in cooperation with -- cosponsored by the -- another specialty section called Sustainable Chemicals, so I would be surprised if there was anybody from outside SOT.

I can't tell you that there weren't lawyers on the call because some SOT members have law degrees as well.

Q. Do you recall saying in that presentation that it's important to address the

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limitations of your work?

A. Yes.

MR. VAUGHN: Objection to form.

A. I probably did.

THE WITNESS: I'm sorry, Brett.

MR. VAUGHN: Slow down a little bit.

A. I probably did. I'd have to go back -- I mean, I might still have the slides for that. I'd have to go back and look at what I said.

Q. What would that mean?

MR. VAUGHN: Object to form.

A. Well, as a scientist, any time you're working, be it in the legal arena, or the regulatory arena, or just as an academic scientist, when you are developing -- you're studying something or your testing something or developing an opinion or a conclusion or you're drawing conclusions about a body of science, you need to consider the information that you're looking at and whether or not there's any limitations to that information as it was gathered that would affect conclusions you might draw.

So for example, in the legal space, the limitations that you would look at, for example, if you were doing causation assessment, would be whether or not, for example, you have been able to draw

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conclusions based on a full array of data, human experience, animal studies, in vitro study, and to be able to look at not only just at the link that may have been shown by epidemiology or observational experience or clinical trials, but whether or not there is a mechanism or a biologic link that you can understand so you know why it is that the -- these two things may be associated, this injury or this effect with this particular exposure.

A lot of what, in this case, is within the IARC document, is a good discussion of the limitations of the different bodies of evidence and the individual studies. So that's the kind of thing you do as a scientist, you look at what's reported, but also any of the strength and weaknesses of the potential pieces of information that you apply.

Q. Do you anywhere -- is there any place in your expert report here where you list what the limitations are of your opinions?

MR. VAUGHN: Object to form.

A. I don't discuss specifically the limitations on my opinions, but certainly, the limitations on my opinions are based upon what it is that I say and what I don't say. And then in addition to that, based upon the type of evidence

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that I cite to, in order to support those opinions.
In the regulatory world, it's a little different than in the basic science world in terms of how you would discuss limitations. When I described to you a few minutes ago, when you talked about IARC, that's kind of a traditional application of discussion and limitations that are applied to the individual pieces of science.
In the regulatory world, the issue that you would come to on limitations is whether or not you have training and experience and/or whether or not you have been able to identify specific regulations or specific standards that you could apply to answering questions that you're trying to answer or opinions that you're going to reach about conduct, responsibility, and what the data says.
It's not quite the same as the discussion of limitations that I would have presented in that seminar.
Q. Your seminar was about being an expert in litigation, right?
MR. VAUGHN: Are you done with this exhibit yet? In so, can we take it down?
MS. MILLER: Sure.
MR. VAUGHN: Thank you.

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Q. Your seminar was about being an expert in litigation, correct?
MR. VAUGHN: Object to form.
A. It was talking about an expert in litigation, and so that's a different area. So -- that I didn't touch on that I can described for you. So in that seminar, we talked a little bit about staying in your lane, and that's what I was describing in my regulatory opinions.
It's the idea you need to understand what your training, experience, and the science can allow you to do in terms of providing expert opinions, and especially with the specific of training and experience. So for example, what it is -- what can you say or what can you analyze based on that training and experience? Is it sufficient to allow you to draw conclusions?
And so that's one of the things I spend a lot of time considering when I agree to take a case, looking at what are the issues, how could I fit in, are there things that are being addressed in this case that fit my training and experience, or not.
And that's how I would approach, and I talked to you a little about bit about that in the seminar, stay in your lane, making sure not to

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overreach based upon the -- for example, if you're looking at a scientific article, making sure that you have considered evidence on both sides; are there papers that teach one thing, and papers that teach the other. So that's what I was talking about, being aware of your limitations. Not everybody can do everything.
Q. I just wanted to know if there's anyplace in your report where you list limitations.
MR. VAUGHN: Objection, asked and answered.
A. I answered that at the very beginning, and then you asked me so some additional questions, so I apologize. I did start, I believe, by answering that question.
Q. Somehow I missed the answer in your colloquy, but can you just tell me, is there anyplace in your report where I can go and see what the limitations are?
MR. VAUGHN: Objection, asked and answered.
A. I started out by telling you that there is not a specific section on limitations in that way. However, when I was describing where you can find my -- where I set forth my methodology, my training

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and experience, and that is a description of what -- why it is I believe I can opine on certain areas. And then of course those judgments would be made, I understand the courts will make certain judgments based upon, you know, what that training and experience and analysis is.
Q. You also stated in your presentation that it's important to acknowledge your biases, do you recall saying that?
MR. VAUGHN: Objection, lack of foundation.
A. I possibly did. I don't remember the context but I possibly did, yes.
Q. Does this sound familiar, "You also need to acknowledge your biases. We all know that we have biases. I have biases as a scientist." Do you recall saying that?
MR. VAUGHN: Lack of foundation.
A. I don't recall that but certainly yes, I --
Q. What are your biases?
A. So --
MR. VAUGHN: Object to form. Slow down just a little bit.
Sorry, Dr. Plunkett.

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A. So bias is that everybody, everybody, based on your background and your experience in life, has -- you see things a certain way. So for me, I may, people may consider that I have a bias when I read a paper if I had funding from industry. So acknowledging bias in publications would be acknowledging any potential conflicts or sources of funding for your work, and that can -- because that can indeed be seen as a potential bias.

If all you ever do is work for industry, there may be certain biases you have because you've never seen things, for example, from the regulatory side, or from the academic side or some other way to look at an issue.

I've been very lucky, I believe, in my training and experience, that I started out at Environ and I was introduced to litigation solely from the defense side. I went out on my own. I did some work in both areas, and now I do a lot of work in drugs and FDA-regulated products from the Plaintiff's perspective.

But I believe that, based upon that training and experience I had at Environ, that I can see things from both sides. It's one of the reasons I still work as a regulatory consultant, because I

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think it's really important to be able to keep your experience and your interactions in a way that you're never seen as just doing this one thing or that one thing. So that's -- that's one of the areas of bias.

The other bias that sometimes comes into play is whether or not, when you design studies, so this came about, this comes about when you actually talk about putting together say, a clinical trial, or an animal study, there's -- may be bias in the way the study is designed.

So as a scientist, you need to consider that because we may not want to design a study to answer a question -- we should always design a study in the best way to answer the question, rather than being prevented from answering the question.

And I believe that was a question that came up during the seminar when we talked about study design.

Q. Okay. You just gave me examples of theoretical biases and biases you don't have. But my question was, what are your biases, do you believe you have any biases?

MR. VAUGHN: Object to form, asked and answered.

A. I believe that everybody has a bias

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solely based on what their experience is, and I was telling you that I believe I've been fortunate in that I've been able to have experience in more than one world. So I've had academic experience, I've had government research experience, I've had consulting solely with industry, and I've had experience working for nonprofit, as well as working in the litigation area for injured parties.

So that, to me, I think, gives me a different view than someone who only ever does the same thing. But certainly, when I said everybody has biases, I mean, I have a bias probably in that I've never been homeless, I've never had to worry about where my next paycheck is coming from; so, if you were to have a conversation and approach me, I might have a bias that's related to that.

I may have a bias because of being a wife and an American woman. There's biases that come into play with that. There is gender bias, there's all kinds of sources of bias. And to me it's just recognizing that bias is a potential issue you need to consider.

So when I approach problems, and I approach a case, one of the ways I try to avoid bias in a litigation world is, I try to approach this, a

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case in the litigation world, just the way I approach a case when I give advice to my regulatory clients.

Q. You said at your presentation that your bias is as a scientist. Were you referring to bias as a white female, to bias as never having been homeless, or were you referring to other types of biases?

MR. VAUGHN: Objection to form, argumentative, lack of foundation. You may go ahead, Dr. Plunkett.

A. So I don't recall the detail, but I'd have to look at my slides. But certainly, a bias as a scientist works would be, a scientist has a certain way of looking at something, right? I have training, I'm a pharmacologist and toxicologist, so I approached my problem that way. I'm not a social scientist, so I may have a bias towards expecting to see certain kinds of information, statistical analysis, where somebody else might come at the problem and not feel those things are so important.

So I don't recall -- I mean, if you have the slides in front of you, we can talk about it. I just don't recall the details of the talk. I really don't.

Q. Do you ever have preconceived notions

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about litigation when you're asked to -- when you are being retained by a Plaintiff's lawyer, do you ever have preconceived notions or ideas about litigation before you accept a retention?

MR. VAUGHN: Object to form.

A. I certainly attempt to not bring any information that I may or may not be aware of to the table when I make that decision. Decisions I make on whether to work in the litigation area have more to do, not with the preconceived notion but with the information that I know is available that I believe I can or can't support.

But certainly, for example, in a case like this, I was aware already of NDMA, so for example, I certainly had an opinion that NMDA is a carcinogen, before the -- before I entered this litigation. However, that doesn't mean that I didn't revisit that opinion by looking across, as I told you, looking across what authoritative bodies and textbooks have shed over the years, how far back in time that went.

So that was a new analysis that I did that wasn't just related to the fact that I was aware that NDMA was a prototypical positive control used in animal studies for cancer, which is something that

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I've been aware of since I was in academics in the '80s.

Q. Do you ever accept a legal case because you have preconceived notions about the substance of litigation?

MR. VAUGHN: Object to form.

A. Not in a brand new area, no. Certainly if I was approached by a lawyer that had a case related to ovarian cancer and talc, I've done so much work and analysis in that area that certainly I have very strong opinions about the risks, but also what the labeling for the product should have been over time.

So I would bring that same view, unless new information came about to change it, I certainly would look for that, so even though I already have that opinion, but that's -- that's a little different. That's -- preconceived notions to me would be more about the issue of the first time you think about a problem, not the same problem that's being presented to you again in the same way.

Q. Okay.

MS. MILLER: I don't have any further questions.

(Continued on following page.)

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EXAMINATION BY
MR. HARKINS:

Q. Hi, Dr. Plunkett, this is Steve Harkins with Greenberg Traurig for the Teva defendants, can you hear me?

A. I can. Nice to meet you.

Q. Nice to meet you, too. You've been going for a little bit. I'm happy to just continue. I just wanted to check and make sure you don't need a second for a break or anything, right?

A. Let's Keep going.

MR. VAUGHN: Thanks, Steve.

Q. All right. So Dr. Plunkett, I represent Teva and obviously you're familiar with Teva and their role in this case as a finished dose manufacturer, right?

A. Yes.

Q. And because we don't have a lot of time left, I just want to be clear, what I'm focused on and what I'm going to be asking you questions about is whether you have or have not formed opinions about the conduct of the finished dose manufacturers in this case, okay?

A. Okay.

Q. It appears that your report is pretty

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focused on ZHP and while there are citations to Teva documents, there are not a whole lot of references directly in the narrative to Teva or Torrent, is that fair?

A. That's probably true.

MR. VAUGHN: Object to form.

A. It's probably true that there aren't many citations to just Torrent, many citations to just Torrent, for example, or just Teva documents, that's true. And the majority, if not all of the company testimony, were ZHP employees, I believe, that I've looked at so far. Maybe there was a Teva or a Torrent person; but the majority of them -- because the facts in this case, you -- Teva, not you, but Teva as a company was using API manufactured from ZHP, so a lot of the information, and I think I mentioned them a couple of times today, in terms of the responsibilities.

Q. Understood, and we'll talk through that. Generally speaking, were you asked to render opinions about the conduct of the finished dose manufacturers in preparing your report in this case?

A. I was asked to address the API and finished dose manufacturers as it relates to my area. So that's different than the expansive to all areas,

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so for example, it's my understanding that other experts are going to handle some of the issues related to Teva and Torrent with regulatory -- some other regulatory compliance issues. But I have considered them as their role the people who were buying and using the API from ZHP.

Q. And what I'm going to attempt to clarify is whether your references to the finished dose manufacturers, and specifically Teva, are intended to either be factual information that's important for your report, or in its contents, talking generally about obligations that would apply to any finished dose manufacture, or if they are criticisms about the specifics about the finished dose manufacturers in this case. And I'll get more specific, but that's generally what I'm trying to figure out, okay?

A. Sure.

Q. You mentioned that there are other experts who have worked on different areas. You've talked about chemistry and CGMPs. Are you aware that there are other experts who are directly addressing the conduct of the finished dose manufacturers?

A. Yes, I believe so. And I'm also aware of, I believe I've read at least one report from one of Teva's experts that's on my list, that was in the

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list that Mr. Vaughn sent around, hopefully you received that, in response to the notice of deposition.

MR. HARKINS: And I'll go ahead, I don't believe the objection responses of the notice have been marked as an exhibit, and if that's the case I'm going to go ahead and mark this and I believe this is now Exhibit 11, is that right?

MR. VAUGHN: I think you're right, Steve.

EXH (Plunkett Exhibit 11, Plaintiffs' Objections and Responses to Defendants' Notice of Deposition of Laura Plunkett, marked for identification, as of this date.)

MR. HARKINS: We'll introduce that. And because you mentioned it, are we using a prefix to that or do I just add it?

MR. VAUGHN: Can we get a time check as we're getting the exhibit up and loaded?

VIDEOGRAPHER: Sure, stand by for that.

MR. VAUGHN: Thank you.

(A pause in the proceedings.)

Q. All right, Dr. Plunkett, the exhibit has been introduced with your objections and responses and if you would like to pull that up there or I can

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screen-share it for you if that would be more convenient. You just let me know.

A. On that one I've seen it before, so if you want to just screen-share it, that's fine.

VIDEOGRAPHER: We're at six hours, 16 minutes.

MR. HARKINS: Thank you. And thanks for the option on the exhibit, Steve.

Q. Doctor, let me know when you can hopefully see the document, I'll go up to the top just to confirm, is this the Plaintiff's objections and responses to the notice of videotaped deposition for you?

A. Yes, that's correct. And I -- I went over this and assisted in terms of responding to the notice of deposition, and I saw this document after it was filed.

Q. All right, and specifically I'm going to go down, I'm interested in just confirming the part that you brought up where you mentioned that you have reviewed a number of additional expert reports including the ones at the end of this paragraph, at the top of page 11 for defense expert reports of Dr. Steven Baertschi, Dr. Roger Lea Williams, and Mr. Timothy Anderson, do you see that?

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A. Yes.

Q. And those are Teva experts, do you recall seeing in those reports?

A. Yes, and Dr. Baertschi is one I certainly recall was, and I believe Dr. Williams as well. Dr. -- Mr. Anderson, I don't recall his in any detail, but -- the ones I remember are ones that may have actually mentioned my name, so I spent more time with those.

Q. Are there any other Teva depositions, reports, or corporate documents that you reviewed in between the time that you completed your report and the deposition today?

A. No. I don't believe so.

MR. HARKINS: I'll go ahead and stop sharing that.

Q. I'd like to go and just talk specifically about the times that you do discuss Teva in your report, and then some other times where you're referring to finished dose manufacturers more generally. Before I go to that, do you feel that you have reviewed sufficient material to form opinions about every aspect of the Teva Defendants' conduct in this case?

MR. VAUGHN: Object to form.

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A. I don't know what you mean by every aspect, but I would -- so what I would say to you is I believe I have reviewed sufficient information to form the opinions I have that apply to finished dose manufacturers including Teva, as I -- as I have put them forth. And again, there are other experts I know that are going into much more detail on some of the other -- the issues that I don't cover. So that may be issue -- you know, may be issues for Teva.

Q. And if there are other experts who are covering this in more detail for Plaintiffs, you would defer to their opinions on those subjects?

A. Well, I just don't go there. That's beyond my opinions, beyond the scope. As far as whether I defer to anybody else, I don't typically defer to somebody, I just say that's something that I'm not doing, unless I mention them specifically in my report and say that, you know, I concur -- like Dr. Hecht, I felt that his report and his, discussion based on my understanding of the chemistry and his discussion of the literature, was such that I wanted to describe it.

Q. Okay. Well, I'd like just to quickly walk through and make sure that I understand where you have referred to Teva. Do you have a copy of

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your report with you?

A. I do, yeah, if you want to tell me where you want to go.

Q. Sure, and I think most of these should be pretty straightforward. If you can go ahead and look on page 35, there is a footnote.

A. Um-hum, yes.

Q. And that reference to Teva, that's just factual information as to their status in the case as a Defendant, right?

A. Yes, and I would say also, on page 4, where a footnote, "Valsartan containing products," I understand Teva makes some of those products, even though I don't necessarily link one specifically to Teva.

MR. VAUGHN: Steve, are you on this screen-share for video purposes or are you okay with it not being on video?

MR. HARKINS: I think it's fine if we're not on video.

Q. But, Doctor, if you could use fuller --

MR. HARKINS: -- or if anybody else needs to see it, let me know. But we're just going to walk through some sections of her report quickly.

MR. VAUGHN: Understood.

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Q. Doctor, turning to paragraph 45 of your report, which I believe is the next referenced directly to Teva --

A. I'm there, yes.

Q. -- and there are two sentences at the end. One says, "It should be noted that all ANDA holders have a responsibility to either perform such risk assessments or to ensure that such risk assessments have been performed in any API they may incorporate into their finished drug products," do you see that?

A. Yes.

Q. And the question I have about that is, is that a statement by you generally that ANDA holders have a responsibility to insure certain things about the API they have incorporated in their finished dose drug products, or is that intended as a criticism of Teva's steps taken to perform risk assessments to insure the quality of their API?

MR. VAUGHN: Object to form.

A. To -- this is as written, a general section of the report, which is here as a general statement about ANDA holders which would apply at Teva, because they are finished dose manufacturers. But if I meant, if I was referring to a specific

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document related to Teva or Torrent, I would cite it and I have not.

In the next sentence I say, "This duty would assure the purity applies to them." So I am saying that they had a duty to ensure purity. And so my criticism obviously would be that they sold product that contained the impurity 'cause those products were recalled as well.

So as a result of that, that would fall as a failure to insure the purity before the products were distributed.

Q. And do you feel that you've reviewed sufficient documents and material to comment and provide opinions on the risk assessments performed by Teva related to the ZHP API?

MR. VAUGHN: Object to form.

A. So I have not done a lot of -- I have done as much investigation as the other experts that are dealing with some of these GMP issues have done into the Teva and Torrent files.

What I will tell you is, the evidence I have seen is that I don't see Teva and Torrent in the documents, because I actually asked for some of these documents, that I haven't seen the evidence, and I haven't seen it discussed in the ZHP documents,

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either, whether they are the kind of conversations or questions from Teva and Torrent that you saw from either Novartis, when they discovered the problem in 2018, when they were looking at qualifying of ZHP for use as an API for finished dose products, or for things that were gone over this morning by -- that I had not reviewed before, by -- gosh, Ms. Miller, Jessica, about the interactions that other companies were having in terms of going back and forth with ZHP. So I haven't seen that evidence. If it exists, you're going to show it to me, I can consider it, but I have not seen that.

Q. Well, Doctor, I'm not interested in things that you didn't review. I'm asking if you feel like, in rendering your opinions, you have reviewed sufficient information, not just to make the general statement that there was a duty for these finished dose manufacturers to perform risk assessments, but have you reviewed sufficient documents to come in and offer opinions in your report and then eventually at trial about whether the finished dose manufacturers, including Teva, adequately performed their risk assessments, have you reviewed those risk assessments?

MR. VAUGHN: Object to form. Asked and

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answered.

A. I have -- the documents that I have seen at this point in time, I feel comfortable allow me to say what I say in my report. So if you're asking me for, is there an opinion that is not expressed in my report, or when I use the word "ANDA holders," if I'm using the general word "ANDA holders," however I'm stating that opinion, that would encompass Teva and Torrent. But my language is very carefully chosen based upon the information and evidence that I have reviewed.

So you were correct in stating that this first sentence you've read was a general statement about what the responsibilities of ANDA holders are.

The second sentence that you didn't read in, where I say in this case, I'm letting you know that it's my opinion that that duty goes to them, too, Teva and Torrent, because those -- and Prinston and ZHP because four of those actually made a finished dose, so it's not just a ZHP opinion.

And then earlier today I made some statements to you that I think if you get to it, back of the back, I do have some specific opinions about adulteration, and as the finished dose being adulterated if it contained an adulterated API. I

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think those are the main areas that I covered that would be Teva and Torrent specific.

Did that help you? I'm just trying to summarize it to get it going, but --

Q. Sure. Let me go ahead and point you, and I'm happy to screen-share if we'd like here, to the appendix that you list the materials that you did consider prior to providing your report in this case.

A. I have it. I have my appendix C, so you want to just tell me which page?

Q. Okay. The first page of the appendix, it's following 47 but unnumbered, listing number of depositions here. Do you see that?

A. Yes.

Q. Now, I'll represent to you that none of these are depositions of Teva corporate employees. If you disagree with that, let me know and I'm happy to explain the identity of any of these individuals.

Do you think that you reviewed any Teva depositions?

A. I reviewed depositions where Teva was in, was at the deposition and may have been even asked for questions; but no, in these depositions, you're correct. These were employees of ZHP and Teva relied on ZHP to produce their API.

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Q. But my question is, you did not review any depositions of any Teva corporate witness, correct?

A. That is correct. If it's not listed here, this is all I have reviewed in terms of corporate witnesses.

Q. And you identified thee reports that were provided last month that you've also not reviewed the depositions of any Teva expert witnesses that have already taken place, correct?

A. I didn't know that any expert witness depositions had taken place. Usually the defense experts don't go until after the Plaintiffs's exhibits go; but if I'm mistaken, I have not. I would actually expect to potentially review that information.

Q. Turning to the next page, there is a section that begins to list the Teva corporate documents that you reviewed. Do you see that, towards the bottom in the right-hand column?

A. Yes.

Q. There are a number of documents here that have "(ECTD)" in parentheses after the description, do you see those?

A. Yes.

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Q. Those are the ANDA files in ECTD format, is that correct?
A. That's correct.
Q. Then there are a handful, one, two, three, four, five, six, seven, eight additional Teva documents on the next page.
A. Yes, that's correct. And it's also some non-ECT documents on the bottom of the second page as well.
Q. Correct. These are all the Teva documents that you reviewed in preparing to render your report in this case, correct?
A. These are all the documents with the Teva Bates but I assume that means, in my experience, they came from Teva's files, that is true. But there are a number of documents in the ZHP discovery that are discussing or may be or would be relevant to Teva. But you're correct, as far as what was in Teva's discovery, these are the only ones that I have.
Q. So for example, in connection with the opinion that you, I believe, have said you intend to offer about the risk assessments performed by Teva and their evaluation of their supplier, you did not review the risk assessment that they performed on ZHP

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and ZHP's process in connection with the process change, did you?
MR. VAUGHN: Objection, form, lack of foundation.
A. If it's not one of these documents, no, I would have not have reviewed it. So you have to tell me, because I don't recall what each of these documents was --
Q. I'll certainly represent to you it is not one of these documents. You did not review that document in preparing to render your own opinion, correct?
MR. VAUGHN: Object to form.
A. I did not, but don't forget the issue that you have here, and maybe this is something I talked about this morning, is that as an ANDA holder, Teva has a responsibility to ensure that their supplier has done all the right things. And given that the supplier didn't do the right things, I haven't seen a document to indicate that Teva questioned them about that. And I did ask about that from the attorneys, and I don't have any documents that I have reviewed at this point in time.
Some of these requests and things came right before my report was filed. But I didn't --

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wasn't given anything.
Q. You didn't feel that Teva's risk assessment evaluating and obtaining information about their supplier's process control change was relevant to whether Teva appropriately evaluated their supplier's process control change?
MR. VAUGHN: Object to form.
A. Given that ZH -- no, I think my opinion is, given that ZHP's risk assessment was ineffective, and in the DMF, which is what Teva and Torrent don't have access to, right, and then not seeing an agreement between Teva and Torrent, and I did look for this, whether or not there was a -- I asked this question, was there a confidentiality or a non-disclosure agreement where Teva and Torrent asked to review the DMF, and it's my understanding that was not the case. So those are the kinds of questions I asked.
So the issue is, if you never reviewed the details of their DMF, then obviously, you can't correct any deficiencies as an ANDA manufacturer that existed. The deficiency started with ZHP but by not having access to those details, and instead relying on representations made by ZHP, where we know that some of those representations were not adequate in

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terms of the work they did, it falls to --
Q. Doctor, during this session, I'm never asking you about the conduct of ZHP and I'm never going to be asking for a response that details the conduct of ZHP. And we have very limited time for the two remaining Defendants, and I am strictly focused on your opinions about Teva's conduct and, by extension, whether you evaluated that conduct for the finished dose manufacturers, okay?
A. Yeah, and that's why I mentioned the ANDA, the nondisclosure because --
Q. You --
A. -- go ahead -- I'm very familiar with NDAs in licensing agreements, when I do due diligence and people are looking at files to understand what's going on. And that's -- that's the reason, so that may be a separate opinion that isn't what you're asking. And I apologize, but I did --
Q. I am certainly not asking about that opinion. I'm just asking about your opinion about Teva's risk assessment and evaluation of their supplier, not to do with ZHP documents. And I just want to confirm, you did not review any of the Teva risk assessments of their supplier, ZHP, correct?
MR. VAUGHN: Object to form.

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A. If it's not one of ones listed, I did not, that is true. And we started there, and you represented and I'll take your representation.
Q. I will represent to you that there was a change control instance report that documented a whole series of steps that Teva took in connection with evaluating the change to the process that eventually generated the impurity. This is not on your list of materials considered, that is also not something that you considered in rendering your opinions about Teva's conduct in evaluating their supplier, correct?
MR. VAUGHN: Object to form, lack of foundation. You may answer.
A. If it's not in my list, I didn't review although I would argue that that area is one that I understand is being covered by other experts in terms of looking at the change control documents and those documents which have to do with GMP compliance, obviously, for the finished dose manufacturer. Because they have separate responsibilities from -- as well.
Q. And you're familiar with the closed portion of the DMF that is not available and visible to the finished dose manufacturer in the course of

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getting an ANDA approved, etc., right?
MR. VAUGHN: Object to form.
A. I am aware that Drug Master Files are typically closed unless companies come to an agreement to share information. That's why I mentioned getting -- I don't know what you call it, a confidentiality agreement, a nondisclosure agreement of information, and that's why I asked, did those exist, and I was told that there was no indication they did in the discovery documents.
Q. Is your criticism of Teva that they failed to seek access to the closed portion of ZHP's DMF?
MR. VAUGHN: Object to form.
A. Yes, given that -- give the situation that existed here, that's exactly right. I mean, again, this is advice I've given to clients before, when they are talking about having responsibility for something else, that another company does that, it's not within their purview. In fact, if you look at -- I know you have limited time, sorry, but in a -- I cite to a document in my reliance materials that is a presentation put on by the FDA about Drug Master Files, and it makes it very clear that you're right, they are closed. But it also indicates the companies

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can make their own arrangements. So it isn't that they couldn't do that, it's just that I don't think it was done based on the evidence I have.
Q. Doctor, are you aware of any indication or evidence that you can point to, and I'm talking specifically about Teva here, are you aware of any piece of information or document that, according to your opinion, should have led Teva to seek access to the closed portion of ZHP's DMF?
MR. VAUGHN: Object to form.
A. I would say that the information that I'm aware of would be the fact that they were referring to the Drug Master Files in their ANDA from ZHP; so in other words, they were referring to the Drug Master File. It's my.
Understanding they didn't have access to it. It would be my advice to take a look so you have an understanding, particularly when the DMF you're referring to was not the one that is -- is not the process that related to Diovan, which was the Reference Listed Drug.
Q. You've not seen any document or evidence whatsoever that Teva was aware of the presence of NDMA or NDEA in Valsartan prior to June 2018, have you?

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MR. VAUGHN: Object to form.
Q. Teva specifically.
A. I don't believe so, no.
Q. There was a statement during the course of your deposition earlier today where you said Teva and Torrent also have duties to evaluate their API suppliers and insure they produce a quality product. Is that effectively a restatement of the opinion that we've been talking about here?
MR. VAUGHN: Object to form.
A. Yes, well -- it's a different way of saying what we already read into the record, that's exactly right. And the reason I stated it this morning was, I wanted to make sure that, since you were going to ask questions, that you knew I wasn't -- if you haven't seen that part of my report, which I assume you had, that I do put a responsibility here in terms of that relationship, that Teva and Torrent have a responsibility for the API as well, because they are a finished dose manufacturer using that.
Q. Turning to paragraph 52 of your report --
A. Yes.
Q. -- I believe here you're referring to

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ANDA holders in the second full sentence where it says, "Yet neither ZHP or any of the other ANDA holders performed the necessary risk assessment for degradation products from ZHP's Valsartan processes. Such risk assessments, if adequately performed, should have led to identification of the potential and actual presence of nitrosamine impurities in ZHP's Valsartan product," you see that there, right?

A. I do.

Q. This situation where you are referring to ANDA holders including Teva and stating an opinion that they should have performed necessary risk assessments for degradation products that -- is that your opinion here?

MR. VAUGHN: Object to form.

A. My opinion is, as I stated, and if you're an ANDA holder that was using ZHP's process and product, yes, I would refer to Teva and Torrent.

Q. As we have already established, you did not review the risk assessment that Teva performed in connection with ZHP's process in forming this opinion, correct?

MR. VAUGHN: Asked and answered.

A. That's correct. The document that you're referring to that I haven't seen, yes, I have

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not -- referring to the change control, what you call the change control document, is that what you called it?

Q. That's another document that you didn't review. The actual risk assessment for the ZHP process which you did not review, you didn't feel that it was important to review that document in coming to your opinion that Teva's risk assessment related to this product was insufficient?

MR. VAUGHN: Object to form.

A. Well, there certainly would be other documents I would consider, but I don't think it would change my opinion based on the facts in this case, which is that I did ask was there some type of a sharing of confidential documents, such as that you could do -- in order to -- in order for you as Teva or -- not you, but in order for Teva as a company or Torrent as a company in my opinion to be able to do a proper risk assessment, they would need to see the details in the DMF.

It's my understanding they did not ask for that access so, as a result of that, they are in a position in relying on the adequacy of risk assessment from ZHP.

Obviously, based on the facts in this

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case, as we know, the ZHP API contained impurities of NDMA and NDEA that are tied to the changes in the process. And based upon, as we talked a lot this morning, based upon what was -- should have been known -- could have been known based on the chemical literature, and then of course looking what Dr. Hecht had said about the foreseeability, that lack of a full assessment in my view was very important to why we got to where we were, which was adulterated products.

But you're correct, I am not seeing the document that you're referring to. I've seen much more information related to ZHP than I have you -- have Teva -- I don't mean you personally, I apologize, than I have for Teva.

Q. And the fact that you've not evaluated Teva's own, not ZHP's, Teva's own risk assessment, or their change control, or the policies that they have put in place around this change, doesn't, you feel, impact your ability to provide an opinion on Teva's conduct related to the risk assessment?

MR. VAUGHN: Object to form. Lack of foundation.

A. I don't believe it does, based on the opinion that I'm providing. But you'll notice that

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I'm only going so far. And as a result, there are other experts that were handling much more detailed reviews and statements about the compliance with GMP or lack of compliance for all of the different parties involved.

Q. I'd like to turn to paragraph 54 of your report.

A. I'm there, yes.

Q. In the second paragraph below where you have quoted?

A. Starting with "For the materials," or starting with "Regarding," or starting with "The Valsartan"?

Q. Below, starting with, "The Valsartan."

A. Yes, I'm there.

Q. The last sentence that starts on that page indicates, "None of the Valsartan ANDAs or supplements disclosed NDMA or NDEA as an impurity." Correct?

A. Oh, yeah, you skipped down, I see where you are. Yes. Yes, that's my statement. You've read that. You didn't read the whole sentence before, but you read the sentence at the end, I see that, yes.

Q. Do you agree, I believe we've already

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discussed that you've not identified anything to indicate that Teva was aware of the presence of NDMA or NDEA in Valsartan prior to June 2018, correct?
A. Based on the documents I've seen, that's my understanding, that they had not gained that knowledge until then, that's correct. But they still have responsibilities which I've tried to lay out in my report.
Q. And, Doctor, I'm being very specific to the actual information that was contained in the ANDA because your final statement in this paragraph is, "The Valsartan finished doses that contained NDMA or NDEA did not comply with the specifications with the ANDAs." I believe that's "within the ANDAs," is that right?
A. Right, because it doesn't mention the presence of the genotoxic impurity.
Q. It's your opinion that the product which met all then-existing specifications for the Valsartan product contained in the ANDA, nonetheless violated those specifications?
MR. VAUGHN: Objection, form, misstates facts in evidence.
A. If the finished dose contained, as I say, Valsartan finished doses that contained NDMA or

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NDEA did not comply with the specifications of the the ANDAs, on this part of that description of the specification for the ANDAs is described by, in a text above, where there was a -- a -- what were you go to call -- a warranty given by ZHP that there was no genotoxic potential, and also, as a result, the specifications don't list as potential genotoxins, even though we know that the -- from the -- the evidence in the case that developed that indeed those processes had the potential to produce NDEA and NDMA; so all I'm trying to say is, it ties in later with this issue of, would the products indeed be deemed adulterated.
And my point is, regardless of whether you're an ANDA holder or you're the API manufacturer, if the finished dose of Valsartan had these genotoxic impurities in them, they would be deemed adulterated, because you can't separate the two.
You can't -- the API is proposing to the finished dose form, unless Teva or Torrent did further purification, which I've seen no evidence that they did, as described in the expert reports of others as well, and no description in the defense expert reports that they did that --
Q. Doctor, I'm not asking about your

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adulteration opinion. I understand that you would like to talk about that. I'm asking about whether it's your opinion that it violates the specifications in the then-existing ANDAs. Have you reviewed the report of Plaintiffs' other expert, Philip Russ?
MR. VAUGHN: Objection to form.
A. Dr. Russ, yes, I've review his report, yes.
Q. Did you review his deposition that he last week, his transcript?
A. No, I wouldn't have had time to review that last week, but I did not. That's the one that you're saying has been available? No, I haven't seen that.
Q. Is it your understanding that Dr. Russ is opining on the conduct of the Teva Defendants, the Torrent Defendants, the specifically the finished does manufacturers in this case?
A. That he has opinions about that? Yes.
Q. Are you aware that Dr. Russ said he would stipulate that the specifications for the then-existing ANDAs were not violated on the record during his deposition?
MR. VAUGHN: Object to form, lack of foundation.

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A. I'm not aware of anything specific he said because I haven't read his deposition. So all I can say is, I would be happy to review his deposition at some point in time, but I have not had a chance to do so. I have seen his report, and I don't recall that language in his report.
MR. HARKINS: I'm going to go and introduce the deposition of Plaintiff's expert Philip Russ as the next exhibit.
EXH (Plunkett Exhibit 12, transcript of deposition of Phillip Russ, marked for identification, as of this date.)
MR. VAUGHN: Can I get another time check while we're getting the exhibit up?
VIDEOGRAPHER: Certainly, stand by.
(A pause in the proceedings.)
Q. And Dr. Plunkett, to move this along, I'm going to go ahead and screen-share.
VIDEOGRAPHER: We're at six hours and 49 minutes.
MR. VAUGHN: Dr. Plunkett, go ahead and download it still so you can see it in context, if you want to see the pages before and after.
Q. Let me know when you're able to see the Exhibit Share.

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A. I can see it, yes.
Q. Starting at the top, the question, "Are you aware that, even at the highest levels of impurities reported in ZHP API anywhere in world the testing showed, according these standards in the compendial specifications, that the impurities were below the reporting thresholds, correct?"
There's an objection. Do you see that question?
A. Yes, I do.
Q. And his response, "I'll stipulate to that, yes. I mean, my concern again isn't about the meeting of specifications."
Do you see that?
A. I do.
MR. VAUGHN: Object to form, incomplete document.
A. I do see that, but going back up to the question that's being asked there, I don't know. I haven't read this entire depo and I haven't talked to Dr. Russ. But when you're using the words, "below" -- "The impurities below reporting thresholds," when you're pointing to the .1 percent and that's how he is -- he is reading that, that's a different question than, and a different opinion than

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what I'm expressing.
I'm expressing the opinion that when the finished dose product contains NDMA or NDEA, it does not comply with specifications in the ANDAs which are not to contain levels of potent genotoxins at any level, up to even above or below .1 percent. That's not part of the specification that it's okay for there to be a genotoxin at a level less than .1 percent.
I don't argue with you that part of the issues here relate to the inadequate work that ZHP may have done. But again, as a finished dose manufacturer, referring to their Drug Master File, and relying on them for their work, there is responsibility that comes with that. And so to me, the lack -- when I make the point that they don't comply, it has to do with just that issue.
So I don't know that Dr. Russ and I are totally in disagreement here, but I'd have to read his deposition to know more about that.
MR. VAUGHN: Is that Exhibit 12, Steve?
MR. HARKINS: Yes.
Q. Doctor, turning to paragraph 55 of your report --
A. Yes?

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Q. -- very last sentence says, "Quality agreements do not absolve finished dose manufacturers from their responsibilities regarding drug quality." Did I read that correctly?
A. I'm looking for where you are. The first sentence doesn't say that.
Q. Very last sentence in paragraph 55.
A. Oh, I'm sorry. Got to go to the next page, okay. Apologize.
Yes, I agree that's what it stated.
Q. Is this a general statement or did you evaluate and have an opinion as to the adequacy of the quality agreements in place for the finished dose manufacturers in this case?
A. It's first a general statement, although I did look at the quality agreements I cited, which some of those, I believe at least one of those, several of those are Teva documents. So -- and the top of paragraph 55, I'm referring to those documents and my review of those documents.
Q. And I understand you reviewed them. I guess my question is, do you have an opinion that is critical of the quality agreements in place for the finished dose manufacturers that you intend to offer in this case?

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MR. VAUGHN: Object to form.
A. Are you asking -- let me ask a clarifying question. Are you asking me, do I have a criticism of specific language or specific responsibilities that were shared with ZHP, why they did that? No. What I'm saying to you is, however, that --
Q. Are --
A. -- what I'm saying is, because you have a quality agreement, that doesn't mean you can run away from your responsibility to ensure that your product is safe for use, doesn't put patients at risk, and indeed is not adulterated.
Q. Understood. You've already answered the question. We can move on to paragraph 57.
Here, in the third sentence you state, "In this case, there is no evidence to show that any of the ANDA holders took actions on their own to warn physicians and their patients about the presence of impurities in Valsartan drug products that were carcinogens." Are you there?
A. Yes.
Q. I'm right in interpreting that as a criticism of the actions taken by the finished dose manufacturers, including Teva?

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A. Yes. Earlier in my report, I referred to, there's the ability for manufacturers to do -- to do healthcare provider letters or direct communication, and I did not see that having been done.
Q. I understand that you didn't see it. You didn't review in forming this opinion any of the recall notices which were sent by Teva, did you?
MR. VAUGHN: Objection to form.
A. Nor am I aware that such existed. I am aware of recall notices existing, yes, but this is a different issue.
Q. Did you review any of the patient-level recall notices that Teva sent in connection with the recall? You didn't review any of those, did you?
MR. VAUGHN: Objection.
A. If they are not in my reliance material, obviously I have not. So you can represent for me that they are there or they are not there.
Q. Did you review any of the information surrounding Teva placing a hold on all products containing ZHP API as of June 21st, 2018, in forming this opinion?
MR. VAUGHN: Object to form.
A. If it was at the FDA website, I -- I may

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have seen things that were specific to them. But if it's not a publicly-available document of the FDA website and it's not listed in my reliance list C, no. And I don't remember ever that I saw at the FDA website. There's a lot there. And there is information in the -- there's a database where you can look at recalled products.
Q. In forming this opinion that the ANDA holders, including Teva, didn't take action to warn physicians and their patients, you did not review any of the documents demonstrating information that Teva communicated to physicians and patients and steps they took to remove product from the market in connection with the recall?
MR. VAUGHN: Objection to form.
A. If they were public documents, I would have. But if not, if they were not public documents, I would not, that's correct. So if you're referring to things that were only in your discovery, then no, and I haven't cited them and I would not have reviewed those.
This also an area that I know that other experts are covering in terms of actions related to the recall itself, but I'm talking about something a little bit more broad than that, than just a recall.

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So I'm talking about specific information about the risks associated with exposure to NDMA and NDEA.
Q. This is not directed at the conduct of the finish dose manufacturers here.
MR. VAUGHN: Object to form.
A. I'm referring -- I'm referring to communication that they could have done directly related to the safety concerns raised that I did not see in their healthcare provider letters, for example.
I'm not disputing that you sent recall notices. You're required to do that, especially since you were doing patient-level recall.
MR. HARKINS: Those are all the questions I have for you, Doctor. I believe that there may be counsel for Torrent who would like to follow up as well.
MR. VAUGHN: Can we get another time check then, because I think we're down to four minutes.
VIDEOGRAPHER: Three minutes left.
MS. NAGLE: I'm going just go ask that we take a five-minute break.
THE WITNESS: That's fine with me, is that fine with you --

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MR. VAUGHN: That's fine. We're going to have two-and-a-half minutes left when we come back.
VIDEOGRAPHER: Going off the record, the time is 7:39 p.m., Eastern Time. This is the end of media unit 6.
(Recess taken.)
VIDEOGRAPHER: We're back on the record. The time is 8:03 p.m. Eastern Time, this is the beginning of media unit 7.
EXAMINATION BY
MS. NAGLE:
Q. Hi, Dr. Plunkett. My name is Brittney Nagle and I represent the Torrent Defendants in this action. I have just a quick cleanup point for you. So do you recall a couple of minutes ago before the break, Mr. Harkins was asking you about paragraph 57 of your report?
A. Yes.
Q. Okay.
A. I don't remember the question but I remember we were talking about it.
Q. Do you recall that he asked you whether or not you had reviewed any of the recall notices or the documentation on the holds that Teva had issued

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with respect to its Valsartan?
A. No.
Q. And I believe that to summarize the answer you gave, you said that you reviewed everything that's listed on Exhibit C in your report, things that were publicly available to be the FDA's website, and that if it was not public, and it's not listed, you did not review it.
A. In that area, that is correct.
Q. Is the same true for Torrent, with respect to their recall notices and other communications about the Valsartan?
A. Yes, it would be the same answer. It's not one of those listed -- I don't know whether you want to represent, but it's not, if it's not there, no, I did not.
MS. NAGLE: That's the only questions that I have for you. Thank you.
MR. VAUGHN: All right, Dr. Plunkett, I have just a few questions. I think we can go without a break, right?
THE WITNESS: Right, that's fine, let's get it done.
(Continued on following page.)

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EXAMINATION BY
MR. VAUGHN:
Q. Do you believe that Teva should have obtained access to ZHP's Drug Master File?
A. Yes, I do.
Q. Do you believe that Torrent should have obtained access to ZHP's Drug Master File?
A. Yes, I do.
Q. Why should the finished dose manufacturers have obtained access to ZHP's Drug Master File?
A. It's the -- the only way that they would be able to assure themselves that the API company, in this case, ZHP, had done a complete and proper risk assessment, especially given that the processes had changed from the TIN process that was part of the Diovan RLD monograph.
Q. In your opinion, could Teva detected have the nitrosamine impurities in ZHP's Valsartan without access to ZHP's Drug Master File?
A. Yes, if they did what Novartis did, because Novartis did that. I have no information that Novartis had access to that.
Q. In your opinion, could Torrent have detected the nitrosamine impurities in ZHP's

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Valsartan without access to ZHP's Drug Master File?
A. The same answer. Based upon what Novartis was able to do, yes, they should have been able to do that.
Q. At any point in time, if Valsartan contained NDMA, would it be deemed adulterated?
A. Yes.
Q. At any point in time, if Valsartan contained NDEA, would it be deemed adulterated?
A. Yes, absolutely.
MR. VAUGHN: I have no further questions.
MS. MILLER: I will have one or two follow-up questions. I promise this break will just be three minutes.
MR. VAUGHN: As long as it's just one or two, because I think, are we at seven hours on the record?
MS. MILLER: We are at seven hours. We have a very long-winded witness --
MR. VAUGHN: I said it's fine.
VIDEOGRAPHER: All right, going off the report. The time is 8:07 p.m.
(Recess taken.)
VIDEOGRAPHER: We're back on the record.

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The time is 8:13 p.m. Eastern Time.
MR. VAUGHN: Before you start, real quick, let the record reflect there is one minute remaining on the record, and we're allowing you two questions. Go ahead, Jessica.
MS. MILLER: It may be three questions, Brett.
MR. VAUGHN: It's over a minute, then.
FURTHER EXAMINATION
BY MS. MILLER:
Q. Dr. Plunkett, I believe Mr. Vaughn just asked you whether at any point in time this Valsartan contained NDMA and and NDEA, would it be deemed adulterated, do you recall that question?
A. Yes.
Q. And your answer is yes, correct?
A. Yes.
Q. What do you mean by "deemed"?
A. That's the regulatory language. When you talk about looking at the actual definition of "adulterated." I may be long-winded, telling you, but essentially in my report, I used that specific language.
Q. Are you saying that the FDA would have deemed it adulterated, or that anyone would have

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deemed it adulterated?
A. That I would deem adulterated consistent with FDA's actions that they took and their decisions that they made in 2019 when they sent the warning letter and made that statement. There is no difference in the facts then than there would have been if they looked at that issue a year earlier.
Q. Are you offering --
MR. VAUGHN: All right, that's a minute-and-a-half. The deposition is done.
MS. MILLER: That's ridiculous, Brett.
MR. VAUGHN: It's not ridiculous --
MS. MILLER: -- the witness, I have a couple of more questions --
MR. VAUGHN: You've asked and answered the same questions over and over. You've asked irrelevant questions about presentations. No. We started this at eight a.m. We've been going for eleven-and-a-half hours. You guys have taken massive breaks throughout the day. We're done.
MS. MILLER: Are you really not going to let me finish asking these questions? Are we going to have to go to the Special Master to ask him to ask five --
MR. VAUGHN: Five -- you said you -- no,

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we done.
MS. MILLER: I'm sorry, it was a few more than two questions, it was a few minutes. Are you really going to --
MR. VAUGHN: Yes, you should have used your time a lot better throughout the day.
MS. MILLER: Excuse me, Brett?
MR. VAUGHN: Do you want me to repeat --
MS. MILLER: You've been taking multiple expert depositions in this matter that have gone slightly over. In fact, more than slightly over, is my understanding. Are you, as part of the professional courtesy, not going to let me finish my questioning? Am I going --
MR. VAUGHN: You're just going to keep going on and on, yeah.
MS. MILLER: Am I going to have to go to Vanaskie?
MR. VAUGHN: You should have reserved time.
MS. MILLER: Brett, we have --
MR. HARKINS: For the record, finished does manufacturers have one question in follow-up to an opinion that is not contained in the expert's report and was raised for the first time on redirect.

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We have one question. I just want to be clear on the record.
MR. VAUGHN: You guys should have reserved some time before spending all of it on your initial questions.
MS. MILLER: Brett, we have a couple of follow-up questions, both from ZHP and from Teva on your redirect. Are you going to let us ask them or are we going to go to Vanaskie and come back another day? It's up to you.
MR. VAUGHN: It's up to you, if you want to go to the Master. But you're not going to ask more questions today.
MS. LOCKARD: That's fine, we'll go to the court. The court has already ruled that when there are multiple defendants, we have an opportunity to spend more than seven hours. There's a ruling on that already. I guess it's our mistake for not clarifying that previously, but we'll file a motion with Vanaskie tomorrow.
MR. VAUGHN: Thank you, Victoria.
MR. NIGH: I want to make it clear, it's Daniel Nigh for the record, that Defendants said that they had two questions before we went on a break where they said it would be a three-minute break,

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ended up being a ten-minute break. And it's getting late in the day, and at this point, two questions is now, I heard many more than two. So that agreement that the Defendants set or proffered to set, that they had two more questions, doesn't sound like they were being honest with that "two more questions."
MS. MILLER: Yes, Daniel, I was being dishonest. Are you actually accusing me of dishonesty now? Because seriously, Dr. Plunkett --
MR. NIGH: Well, sounds like you were inaccurate. Let's go ahead and read -- read -- inaccurate about your two minutes, two questions. That was the agreement. Can you not interrupt me, please?
MS. MILLER: Could you please not accuse me --
MR. NIGH: Don't get into the whole dishonesty. I didn't say dishonest. I didn't -- I didn't accuse you of dishonesty, I said it wasn't honest. There's a difference between the two -- no, no I didn't.
MS. MILLER: You accused me of being dishonest --
MR. NIGH: I said it wasn't an honest statement --

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MS. MILLER: I did not know --
MR. NIGHT: I said it was not an honest statement. To make it clear -- you keep interrupting me.
MS. MILLER: Wait a minute, no. Because I -- accused of dishonesty and that is not acceptable. First of all, my first question -- excuse me, you can talk after I'm done.
MR. NIGH: No, no, no. No, to make it clear -- can you stop interrupting me?
MS. MILLER: You're interrupting me now. My first question --
MR. NIGH: To make it clear, I will change my statement to "inaccurate statement."
MS. MILLER: My first question was, "Do you recall him asking you this question." Are you counting that as one of my two questions? Seriously? I was making sure that Dr. Plunkett knew where we were. That was not a question. I was completely honest and based on her answer, I had to complete the line of questioning. I had about three minutes left, at most. And you guys have decided to turn this into a world war, and that's fine. We'll go to Vanaskie, but --
MR. NIGH: It's not a world war.

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MS. MILLER: It is 8:18 and I would have been done by 8:21. And if you're not going to let us do that, that's fine. We'll go to Vanaskie, but I would like to be clear for the record that assuming -- oh, now you're interrupting me? Assuming that Dr. Plunkett did not give one of her long-winded responses, I would have been done by 8:21.
MR. VAUGHN: You've asked the same question over and over again. You would have done that, too.
MS. MILLER: Thank you very much for your assessment of my questions.
MR. NIGH: Let me reiterate what I said, I will reiterate what I said before we went to the break. Defense counsel said that they would have two questions. Defense counsel clearly had more than two questions, so it was an inaccurate statement. We allowed you to go forward based on your representation that you had two more questions, and the record is clear that there were clearly more than two questions. And that's when Mr. Vaughn shut down the deposition. Thank you.
MS. MILLER: Everything you just said was inaccurate, and that's fine. Because I've now been accused of dishonesty. You are now telling me

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that one of my two questions was, "Do you recall Mr. Vaughn asking you that question," which was obviously a setup to my questioning. That was not a question. I am not -- are you guys going to require us to go to Vanaskie or not? Just let us know, or would you like to go three more minutes and be done?
MR. NIGH: Even if you don't include that question or the question after it, you still would have asked two questions.
MS. MILLER: Are you -- would you like to go three more minutes and be done, or go to Vanaskie? I'm asking you which you prefer.
MR. NIGH: I think Mr. Vaughn has already been clear on that.
MS. MILLER: Mr. Vaughn, would you like to go three more minutes and be done or do we need to go to Vanaskie?
MR. VAUGHN: I think we're done. We don't compromise compromises.
MS. MILLER: And you're going to deny Steve's ability to ask his questions as well?
MR. NIGH: I think what we did, and Mr. Vaughn was just clear, he said you could ask two more questions based on your representation that defendants had two more questions. Period. No more

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than --
MR. HARKINS: I represented that we had one question based on an opinion which was not offered in the witness' report or at any time during her direct testimony. It is one literal question. I understand that you were saying we will not be able to ask that, so we'll file a motion tomorrow.
MS. MILLER: All right, have a good night.
VIDEOGRAPHER: All right, we are off the record at 8:21 p.m. Pacific time and this -- I'm sorry, Eastern Time, and this concludes today's testimony given by Dr. Laura M. Plunkett. The total number of media used was seven and will be retained by Veritext.
(Time noted: 8:21 p.m.)

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C E R T I F I C A T E.

I, DAVID LEVY, a certified court reporter and notary public of the State of New Jersey, certify that the foregoing is a true and accurate transcript of the stenographic notes of the deposition of said witness who was first duly sworn by me, on the date and place as hereinbefore set forth.

I FURTHER CERTIFY that I am neither attorney, nor counsel for, nor related to or employed by, any of the parties to the action in which this deposition was taken, and further that I am not a relative or employee of any attorney or counsel in this place, nor am I financially interested in this case.

IN WITNESS WHEREOF, I have hereunto set my hand this 17th day of January 2023.

DAVID LEVY, CRR, RPR, CLR
LICENSE NO. 30X100234000

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J U R A T / E R R A T A

I have read my testimony in the foregoing transcript and believe it to be true and correct with the following changes:

PAGE	LINE	FROM	TO

_____ _____
WITNESS SIGNATURE DATE

Subscribed and sworn to before me this ____ day of _____, 20____

Notary Public of the State of_____.

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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